UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	**MD-15-02641-PHX-DGC**
	Phoenix, Arizona
	May 25, 2018
Doris Jones, an individual,	
Plaintiff,	
v.	CV-16-00782-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 8 - A.M. SESSION

(Pages 1622 - 1754)

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EXAMINATION

EXHIBITS

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EXHIBITS

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EXHIBITS

08:30:08 **P R O C E E D I N G S**

(Proceedings resumed in open court outside the presence of the jury.)

08:31:54 THE COURT: Thank you. Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

THE COURT: Counsel --

Traci, this mic's not on. It's working, it's just

08:32:11 not on.

THE COURTROOM DEPUTY: Okay.

THE COURT: Do you have matters you want to raise before we get started this morning?

MR. CLARK: Your Honor, the plaintiff has a couple,

08:32:24 but we'd prefer not to be accused of monopolizing the time, so we'll go second today.

THE COURT: How about from the defendants?

MR. NORTH: We don't have anything this morning, Your Honor.

08:32:33 THE COURT: Go ahead, Mr. Clark.

MR. CLARK: Your Honor, the first thing on our agenda was to take a status from the Court. I think you deferred decision on the 2015 FDA warning letter. We're waiting to see whether you felt it was relevant. We do think it is relevant,

08:32:48 Your Honor, in light of a number of things, particularly the

08:32:51 discussion of reporting, underreporting, symptomatic, asymptomatic.

It's a heavily redacted version, as the Court will recall. We do think that is important because it talks about 08:33:05 things like why filters were scheduled to be removed. There was no disclosure of potential complications related to leaving them in the patient due to failed removal.

So those are all issues that have been kind of pervasive and peppered throughout the evidence in this case, 08:33:18 and we think that this redacted letter is relevant.

I would add that looking at the Court's May 14, 2018, Proposed Final Jury Instructions, which is document 11077, one of the things the jury will be asked to look at in deciding the design issues is whether there was FDA activity around the 08:33:44 product. Action or inaction.

We've heard a lot of evidence in the last couple of days about FDA activity and Bard working with the FDA. So we think that to balance that, this is important for the jury to have that additional perspective.

08:33:59 THE COURT: Okay. I understand what you're saying. I am not yet prepared to rule on that. I want to hear another day or two of the defense case and then I'll rule.

MR. CLARK: Thank you, Your Honor.

THE COURT: I expect I'm going to come out where I 08:34:10 did in Booker, but I want to hear a bit more of the defense

08:34:14 case before I make that final decision.

MR. CLARK: Oh, yeah. The parties are working on the 1006 summary. We have provided a draft to defendants. They're reviewing it. We expect to have resolution on that 08:34:30 early next week. We also are working on the various redactions and hope to be in a position early next week to make the appropriate substitutions with the clerk.

The only other issue, Your Honor, for this morning is with Ms. Allen's testimony. There may be a number of exhibits 08:34:47 and we had reached an agreement in Booker concerning redactions and hearsay within hearsay, things like that. So we will be probably not objecting to a number of those, but if you hear us say subject to the agreement or subject to redactions, that's what we're referring to.

08:35:01 THE COURT: Okay. Okay.

Anything else we need to discuss?

MR. STOLLER: One thing, Your Honor. Before Mr. Chanduszko is on this morning and we resume cross-examination, I'd like to raise with the Court an issue 08:35:19 with respect to the ruling on references to other litigation.

We heard yesterday Mr. Chanduszko testified on direct that he believes electropolishing improves filter -- I'm sorry, fatigue and fracture resistance of the filter, and not only does he believe it, but we have tests, data, that clearly 08:35:39 shows it.

08:35:39 That testimony, Your Honor, is in conflict and contradicts his testimony he gave in the Booker trial. And I know we have been pretty good about not mentioning trials, and I wouldn't ask the Court for leave to mention the trial, but 08:35:53 we do think it's relevant that he did that and he has conflicting testimony in cases involving different products.

It's akin to testifying in a case, one case, in saying the light at the intersection was green when it's beneficial for it to be green, and in another case for you to 08:36:11 say red or yellow in a case where it's not to your advantage for the light to be yellow -- excuse me, green.

The fact that it was a G2 case we think is relevant to his testimony and to his credibility, and so we would ask leave to be able to refer it. Not to the trial, but then 08:36:25 generically to another case involving a G2 device.

THE COURT: Well, that's referring to another case against Bard; right?

MR. STOLLER: I understand that, Your Honor. That's why I'm raising the issue and -- but I said not to refer to it 08:36:38 as a trial, but, instead, as testimony in another case. And I'm happy to use the word "matter" instead, but I don't think that makes a substantive difference.

THE COURT: Explain to me -- explain to me why you think that's an important way to phrase it as opposed to 08:36:56 simply saying "haven't you testified before that," and then

use his in- -- what you view as inconsistent testimony.

MR. STOLLER: I think there is a substantive distinction between testimony that is merely inconsistent and where the inconsistencies inure to the benefit of the person testifying or the company testifying.

As I said, it's a different scenario where I testify in one case and say the light was green and it's to my benefit that the light is green.

Here, Bard argues, it's to their benefit, that this device was electropolished. In the G2 case --

THE COURT: Let me interrupt you. Can't you say, "Didn't you testify before when you were testifying about the G2 product that," and then you use it?

MR. STOLLER: I'm fine with that, Your Honor.

THE COURT: That avoids referring to another case or another trial.

MR. STOLLER: I'm fine with that, Your Honor.

THE COURT: Okay. I think that allows you to make your point.

MS. HELM: That was going to be my suggestion, Your Honor.

THE COURT: Okay.

Anything else?

Okay. In terms of the time today, we are at 35 and a half hours as of today, 35 hours and 28 minutes, which is just

about where we should be. So I think we can break at 4:00 to deal with jury instructions today and that will allow everybody to finish a little earlier. So I'll tell the jury we're going to go to 4:00.

08:38:36 Okay. Thanks. I'll come in when the jury is in.

MR. NORTH: Thank you, Your Honor.

(Recess was taken from 8:38 to 9:00. Proceedings resumed in open court with the jury present.)

THE COURT: Morning, ladies and gentlemen.

09:00:55 THE JURY: Good morning.

THE COURT: We are going to resume with the cross-examination of Mr. Chanduszko, and we're going to go to 4:00 today and break at 4:00. The parties and I need to work on jury instructions and we better get started at 4:00 because

09:01:14 that takes some time. So we'll be excusing you at 4:00 today.

Go ahead.

MR. STOLLER: Thank you, Your Honor.

CROSS-EXAMINATION (CONT'D) - ANDRZEJ CHANDUSZKO

09:01:23 ANDRZEJ CHANDUSZKO,

recalled as a witness herein, after having been previously sworn or affirmed, was examined and testified as follows:

C R O S S - E X A M I N A T I O N (CONTINUED)

BY MR. STOLLER:

Q Good morning, Mr. Chanduszko. Thank you for coming back

this morning.

I'd like to start this morning in terms of your testimony about where you ended yesterday when Ms. Helm was examining you.

And I believe you testified yesterday that you believe that electropolishing the Eclipse filter improved the fatigue or fracture resistance of the filter, and not only do you believe that but you have test data to show that. Do you recall that?

A That is correct.

Q Okay. I'd like --

MR. STOLLER: Gay, could you bring up the trial testimony.

BY MR. STOLLER:

Q Mr. Chanduszko, you've testified previously about electropolishing; correct?

A Yes, that's correct.

Q I'm going to read some of your prior testimony when you were testifying about the G2 filter.

"Question: Well, do you agree electropolishing can help with fracture resistance? Yes or no."

"Answer: I'm afraid I can't answer it yes or no. I know it can help and I also know it can hurt."

Did I read that correctly?

A Yes, that's correct.

09:02:29 Q And that's when you were testifying about a G2 filter; correct?
A Correct.
Q Let me ask you --
09:02:37 A And I think --
Q Sir, there's no question pending.
I want to ask you about the tests you referenced yesterday.
MR. STOLLER: And, Gay, could you pull up
09:02:49 Exhibit 8574, please.
BY MR. STOLLER:
Q And let me ask you this: The tests that you referenced in your testimony, those were in existence at the time you gave the testimony we just read. True?
09:03:02 A I believe so. Without looking at the dates I'm not sure, but I believe so.
Q Well, the tests you were talking about were tests that were done in 2009. True?
A Probably around that time.
09:03:13 Q And that testimony we just looked at was much more recent than that. True?
A Yes. That would be my best guess.
MR. STOLLER: Your Honor, we move into evidence Exhibit 8574.
09:03:32 MS. HELM: No objection, Your Honor.

09:03:33 THE COURT: Admitted.

(Exhibit 8574 admitted.)

MR. STOLLER: May we display to the jury?

THE COURT: Yes.

09:03:39 MR. STOLLER: Thank you.

BY MR. STOLLER:

Q Mr. Chanduszko, you have in front of you on the screen what's been marked as Exhibit 8574 to this proceeding. This is a cyclic fatigue testing of the electropolished Vail filter

09:03:52 wire test.

Do you see that?

A Yes, I do.

Q And this is the test report for that test; correct?

A Yes.

09:04:04 Q And the Vail filter wire, Vail was another name for Eclipse. True?

A Yes.

Q And this is one of the reports you were referencing in your testimony. True?

09:04:17 A Most likely, yes.

MR. STOLLER: Gay, would you go to the last page, please.

BY MR. STOLLER:

Q And I believe the jury has seen this before in Mr. North's

09:04:27 opening, but there's a chart there that indicates 5 percent

improvement in fatigue life.

Do you see that?

A Yes, I do.

Q Now, sir, isn't it the case that this test is not a test of the wire itself, but just of the area of the wire that forms the hooks?

A No, that's not correct.

MR. STOLLER: Let's look, Gay, if you would go to page 3 of the exhibit.

And look first under "Purpose."

BY MR. STOLLER:

Q And, sir, it states: "The purpose of this study was to compare the fatigue life of the electropolished Vail filter wire," and there's the number in parentheses, "to mechanically ground G2X wire," with more numbers, "by cyclically bending the ground portion of the wire."

Did I read that correctly?

A Yes. So I actually got confused. There are two tests that are similar and obviously I didn't read the document so I made a mistake. That is correct. That is a -- the test on the wire that is used to make the filter.

Q This is the test of the wire portion relating to the foot of the filter, or the hook of the filter. True?

A The main part of it, yes. I mean the whole wire is tested, I think, with maybe emphasis on the wire that forms

09:05:51 the hook.

Q Sir, I'm going to ask you, as I did yesterday, I've got limited time, so if I ask a yes or no question, please answer it yes or no. If you can't, just tell me you can't answer it.

09:06:00 Okay?

A Okay.

Q Okay. This test tested the area of the wire that forms the filter hooks. True?

A Partially true.

09:06:13 MR. STOLLER: Well, let's go to the second paragraph under "Background," if you would, please, Gay.

BY MR. STOLLER:

Q And I'm going to direct your attention to the sentence that starts in the second line with "However."

09:06:25 It says: "However, the most evident improvement to the surface finish will be along the tapered and smaller diameter sections of the wire that are formed by the grounding operation. This is because the marks inherent to the grinding operation wire will be smoothed by the polishing process."

09:06:45 I'm going to focus your attention right here, sir.

"This portion of the wire forms the filter hooks in the finished device and, as such, this test evaluated fatigue life of the Vail wire in this area in comparison to the G2X filter wire."

09:07:02 Did I read that correctly?

09:07:04 A Yes.

MR. STOLLER: Let me ask, Gay, would you next please pull up Exhibit 8359.

Your Honor, I move that into admission -- into

09:07:24 evidence, excuse me.

MS. HELM: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 8359 admitted.)

MR. STOLLER: May we display, Your Honor?

09:07:31 THE COURT: Yes.

MR. STOLLER: Thank you.

BY MR. STOLLER:

Q Mr. Chanduszko, you should have on your screen in front of you what is Exhibit 8359 to these proceedings, which is

09:07:43 entitled "DV&V Vail Arm Fatigue Evaluation Test Report."

Do you see that?

A Yes, I do.

Q And this is the other test you were referring to when you talked about the tests of electropolishing in your testimony

09:07:54 yesterday. True?

A That's the test for the arms.

Q So the answer to my question is yes?

A Yes.

Q And this is, again, and we talked about it yesterday, this

09:08:03 is the saluting arm test. True?

09:08:06 A That's one name for it. But the other name here is cyclic arm fatigue.

Q But as the jury's heard it, as we described it yesterday as they heard it referred to a number of times, it's the

09:08:17 saluting arm test where you move the arm up and down to perform some more extreme movement in the arm. True?

A Correct.

Q Okay. And let's look --

MR. STOLLER: And, Gay, could you go to the last

09:08:31 page. Let's look under "Conclusions and Recommendations."

BY MR. STOLLER:

Q And I believe the jury has also seen this before in Mr. North's opening. And there under the Conclusions it says in the second sentence: "It is concluded that the Vail filter

09:08:47 arm fatigue life is significantly greater than that of G2X filter arms."

Did I read that correctly?

A Yes. That's correct.

Q It says: "On average the Vail filter showed a 60 percent

09:08:59 increase in cyclic arm fatigue life when compared to the G2X filter."

Did I read that correctly?

A Yes. That's correct.

Q And this is the evidence on which you rely for the

09:09:09 increased filter -- sorry -- fatigue resistance of

electropolishing in the Eclipse filter; is that correct?
A That is one of at least three tests, yes. That's correct.
Q Let's talk about very quickly what this test is. You indicated already this is the saluting arm test. True?
A Yes. Correct.
MR. STOLLER: Gay, could we go to what is page 5 of 9. Thank you, you're already ahead of me.
BY MR. STOLLER:
Q These are the results of that test; correct?
A Yes, that's what it looks like.
Q And if we look at the top -- let's start at the bottom on if we start at the bottom, in table 4 for the Vail filter it gives an overall average of 719.
Do you see that?
A Yes, I do.
Q And that's an average of the number of cycles it took in this test for the arm -- before it broke; correct?
A Yes.
Q And that's one of the relevant criteria used to come to the conclusion in this test; correct?
A The criteria was that the Eclipse filter has more of a fracture resistance than G2.
Q Well, the criteria you compared was the average number of cycles before it fractured in the G2X versus the Vail or the

Eclipse. True?
A Yes, that was the specific measure.
Q So this is the specific measure that you used for the Eclipse. True?
A Correct. For both filters, actually.
Q Well, the 719 is for the Vail or the Eclipse; right?
A Yes. That's the result for the Vail.
Q But based on 15 different filters; correct?
A Yes, that's correct.
MR. STOLLER: Can we go to the top chart, Gay, please. Thank you.
BY MR. NORTH:
Q And your calculation there for the G2X was 440; correct?
A That's correct.
Q Again, based on 15 filters?
A Yes.
Q Now, you had run the saluting arm tests on both the G2 and the G2X prior to those devices being released to the market; correct?
A That would be my best recollection.
Q It was the same test. You deform the arm by moving it up and down, I believe it's a half inch in either direction; correct?
A Yeah, roughly.
Q Okay. And if we look --

09:11:20 MR. STOLLER: Gay, could you go to page 2 of 9, which is 3 of the exhibit, I think.

BY MR. STOLLER:

Q Under References, number 4.6, there is a reference there

09:11:33 to TR-7 -- I'm sorry, TR-07-07-04.

Do you see that?

A Yes, I do.

Q And it says: "G2 Express filter arm fatigue comparison study"; correct?

09:11:47 A Yes.

Q That's the G2 saluting arm test?

A G2 Express.

Q I'm sorry, you corrected me. Thank you very much.

That's the reference to the G2 Express saluting arm

09:12:00 test; yes?

A Yes.

Q And, so, when this test report for the Eclipse saluting arm report was put together, the author of the report and the team looked at the G2 Express saluting arm test report;

09:12:13 correct? That's what it means to be referenced here; right?

A The list as a reference mean this test is relevant to the current test.

Q That test, the G2 Express filter arm fatigue comparison study, is relevant to this test of the Eclipse. True?

09:12:30 A Yes.

09:12:31 Q Okay. Let's take a look at that. That is Exhibit 5385?

MR. STOLLER: Your Honor, we would move into evidence Exhibit 5385.

MS. HELM: No objection, Your Honor.

09:12:47 MR. STOLLER: May we display to the jury?

THE COURT: Admitted.

(Exhibit 5385 admitted.)

THE COURT: And you may display.

BY MR. STOLLER:

09:12:52 Q Mr. Chanduszko, what you have in front of you as Exhibit 5385 is the G2 Express filter arm fatigue comparison study that we just saw referenced in the Vail Eclipse saluting arm study. True?

A That's what it looks like.

09:13:10 Q Well, you're familiar with this document, aren't you? You've seen it before.

A Yes, I've seen it before.

Q You've read it in your role as one of the people at Bard who was working on IVC filters?

09:13:21 A Yes. Back when it was done, yes.

MR. STOLLER: I'd like to, if we could, Gay, move to what is page 6 of 11 of the report. I think it is 7 of the exhibit. Thank you.

BY MR. STOLLER:

09:13:34 Q These are the results of that study, correct, sir?

09:13:40 A Yes.
Q If we look in the top box, Table 4, G2 Express Filter Results. These are the results of that same saluting arm test of the G2 Express in 2007; correct?
09:13:55 A That's what it looks like.
Q And there, in that test, it looks like, again, 15 samples; yes?
A Yes.
Q And in that test the average fracture, place of fracture,
09:14:07 was 668.3.
Do you see that?
A Yes, I do.
Q Now, do you recall, sir, anyone at the time when you came out with the results of the Eclipse fracture test anyone on
09:14:22 the team saying, hey, you know what, this 60 percent result, maybe there's a problem there because we did the same test two years ago and the number of average cycles before the G2X broke in that test was almost the same as we got for the Vail test.
09:14:39 Do you remember having that conversation?
A No, I don't remember.
Q Did anybody say, hey, you know what, maybe there's a problem here and we should look further into whether or not the tests that we're relying on to say that there's 60 percent
09:14:55 improvement in the fracture resistance might not be accurate

because we know from the very same test of the very same device two years earlier we got a very different result.

Did anybody raise that issue?

A I don't remember that.

Q Did anyone say, hey, maybe we should run more tests to see if our data is accurate if we're going to make a claim that this is actually improving filter resistance -- or fracture resistance?

Anyone say, we should run the test more times, figure out what the difference is here why we're coming up with different results?

A No, not necessarily.

Q Okay. We were talking about the saluting arm test here for the G2 Express. And yesterday we were talking -- when you and I ended at the end of the day we were talking about the G2 and its saluting arm test. Do you recall that?

A Yes.

Q And I had asked you -- started to ask you a question yesterday about whether you had run a finite element analysis for that same loading condition. Do you recall that?

A On the G2 filter?

Q Yes, sir.

A Yes.

Q And you did not run prior to release an FEA for the G2 under that loading condition, did you?

09:16:23 A No, there was no need for that.

MR. STOLLER: Let's pull up Exhibit 1295, please, Gay. Thank you.

Your Honor, this is in evidence, I believe.

09:16:38 THE COURTROOM DEPUTY: Yes, it is.

MR. STOLLER: May we display it to the jury?

THE COURT: You may.

MR. STOLLER: Thank you.

BY MR. STOLLER:

09:16:45 Q Sir, this Exhibit 1295 is an e-mail from Micky Graves to Charlie Simpson regarding historical FEA analysis.

Do you see that?

A Yes, I do.

Q If you look at the very bottom of this page, the first of

09:16:59 the e-mails is from you; correct?

A That's correct.

Q Then the second e-mail just above that is an e-mail from Mr. Simpson back to you and it says, "Andre, thanks. Do we have the same analysis for G2?"

09:17:12 Do you see that?

A Yes, I do.

Q So he was asking you whether you had an FEA analysis for the G2; correct?

A That's what it looks like.

09:17:27 Q Let's go to the top e-mail.

09:17:28 And there Mr. Graves says, "No, but we intend to get a similar study completed. The team agrees."

Then he says the following in the second paragraph: "I have talked with Andre" -- and that's you; correct?

09:17:44 A Yes, that's me.

Q "I have talked with Andre as to why we did not do this test for the G2 in the beginning. His reason was that the G2 longer arms with a wrist would not engage the cava wall and would not have a saluting arms" -- "would not have saluting arms."

09:18:02 Did I read that correctly?

A Yes.

Q "Therefore, the engineering staff did not see the need to run an FEA for a saluting arm failure mode that was not realistic."

09:18:13 Did I read that correctly?

A Yes.

Q "They felt the data would still fall out of the acceptable range of the Goodman fatigue evaluation."

09:18:24 Do you see that?

A Yes, I do.

Q Next paragraph.

"I am not satisfied with that answer at all. Just because we didn't think the answer would support our design change as a viable option we chose not to run the test."

09:18:34

09:18:39 Did I read that correctly?
A Yes.
Q Let me ask to you skip down a couple lines there. It says -- I'll just read from there.
09:18:48 "We settled on the arm bend fatigue tester to give us an answer that we are now 12 times more fracture resistant under specific loading conditions."
Do you see that?
A Yes, I do.
09:18:59 Q And the jury has heard the testimony from Mr. Tessmer about that test, I believe. But let me ask you this one.
He then says, "The bigger question still is, is 12 times more resistant enough? We are stuck answering the same question a year later in order to even consider trimming the
09:19:19 wrist option."
Correct?
A Yes, that's what it says.
Q And so that test was not run, was it, that HEA?
A We ran the actual physical test, so the FEA was really
09:19:31 not needed.
Q Mr. Graves says, "I'm not satisfied with that answer. Just because we didn't think the answer would support our design change as a viable option, we chose not to run the test."
09:19:47 That's what he said; correct?

09:19:50 A That is exactly what he says, yes.
MR. STOLLER: Thank you. No further questions.
THE COURT: Redirect?
MS. HELM: Very briefly, Your Honor.
09:19:56 R E D I R E C T E X A M I N A T I O N
BY MS. HELM:
Q Mr. Chanduszko, at the time the G2 went to market, had Bard perfected the electropolishing process?
A No. We did not have an electropolishing process.
09:20:18 Q So as you testified yesterday, could it have been detrimental to the G2 to electropolish it when you didn't have the process perfected?
A At that time, yes, absolutely, it could have been.
Q And Mr. Stoller showed you some testing that was at
09:20:36 different time periods. When you're doing testing, is the side-by-side comparison of the two filters that you're testing at the same time the most important aspect?
A Yes, it is, because there could be changes in the test setup or fixtures, so typically we try to do the testing side
09:20:55 by side to eliminate any possible changes. So both devices are tested in exactly the same way.
Q And did the side-by-side comparison between the G2 and the electropolished Eclipse show that the electropolishing had a benefit for fatigue resistance?
09:21:15 A Yes, it did.

09:21:16 Q And his last line of questioning, Mr. Stoller showed you an e-mail where Micky Graves disagreed with your analysis; is that right?
A Based on what he says, yes. I don't remember the
09:21:28 particular conversation, but, yes, based on the e-mail.
Q Were you involved in the actual physical testing of the G2?
A Yes, I was.
Q Mr. Graves was coming in and asking questions after the
09:21:40 fact; is that -- was Mr. Graves coming in and asking questions after the fact?
A Yes.
Q Is it healthy for engineers to disagree and to brainstorm and have different opinions and approaches to evaluation of
09:21:53 their product?
A Absolutely.
Q Is that what was going on between and you Mr. Graves?
A That's what it looks like.
MS. HELM: Thank you. No further questions,
09:22:04 Your Honor.
THE COURT: All right.
Thank you, sir. You can step down.
MR. STOLLER: Your Honor, might we approach?
THE COURT: You may.
09:22:16 If you want to stand up, ladies and gentlemen, feel

09:22:18 free.

(Bench conference as follows:)

MR. STOLLER: That last line of questioning, particularly the questioning about his testimony, suggested 09:22:23 that his testimony with respect to the electropolishing was at the time the G2 was in development. We have specifically avoided talk about time periods of that. Based on our conversation this morning, I restricted my question with respect to his testimony on electropolishing just to ask about 09:22:39 the G2. I didn't talk about the fact it was a month ago, which is highly relevant given that -- particularly given that she just asked him whether electropolishing was possible, and his testimony about that relating to the timing. It's very critical.

09:22:55 THE COURT: I'm not understanding where you're going with this.

MR. STOLLER: I'll slow down.

THE COURT: Well, no, just tell me what the end point is. The end point --

09:23:00 MR. STOLLER: The end point is we should be able to come back and ask Mr. Chanduszko that the testimony he gave that I asked him about to start today was six weeks ago. Two months ago. Because her questioning --

THE COURT: But you did say, you did establish --

09:23:15 MR. STOLLER: I said more recently.

09:23:17 THE COURT: You established in your questioning that it was much -- I think you used the phrase much more recent than 2009. Right?

MR. STOLLER: Yes.

09:23:27 THE COURT: And the G2 was 2005. So it seems to me you established the point that his testimony was well after the G2 was on the market.

MR. STOLLER: Fair enough, Your Honor.

THE COURT: Okay.

09:23:39 (Bench conference concludes.)

THE COURT: Thank you, ladies and gentlemen.

MR. NORTH: Your Honor, at this time the defendants would call Ms. Shari Allen O'Quinn to the stand.

THE COURTROOM DEPUTY: Ma'am, would you please come

09:24:08 forward and raise your right hand, please.

SHARI O'QUINN,

called as a witness herein, after having been sworn or affirmed, was examined and testified as follows:

THE COURTROOM DEPUTY: Will you please state your

09:24:19 name and spell it for the record, ma'am.

THE WITNESS: Shari, S-H-A-R-I, O'Quinn. O-Q-U-I-N-N.

THE COURTROOM DEPUTY: Thank you.

D I R E C T E X A M I N A T I O N

BY MR. NORTH:

Q Good morning, Ms. O'Quinn.

A Good morning.

Q Could you tell the ladies and gentlemen of the jury whether you were ever employed by Bard Peripheral Vascular?

A Yes, I was.

Q How did you work at Bard?

A For about four years.

Q What years were those?

A Approximately 2003 to 2007.

Q And that was at Bard Peripheral Vascular, the division in Tempe, Arizona?

A Yes.

Q What was your title at Bard when you left in February of 2007?

A It was the director of regulatory affairs and clinical research.

Q Please describe for the jury your roles and responsibilities at Bard as the director of clinical and regulatory.

A Yes. I was a leader of a team of people who conducted all of the clinical research studies and compiled all of the data that we submitted to the FDA and other regulatory agencies for approval of our products.

09:25:45 Q What sort of products did you work with while at Bard Peripheral?
A I worked with stents, stent graphs, vena cava filters, biopsy products. A variety of cardiovascular and
09:25:59 biopsy-based products.
Q And which generations of Bard inferior vena cavas did you work with?
A I worked with the Simon Nitinol, the Recovery, and the G2.
09:26:14 Q Did you ever work with the Eclipse filter?
A No, I did not.
Q Describe for the jury, if you will, the level and amount of interaction you generally had with the FDA while you were working at Bard.
09:26:29 A While I was at Bard, we interacted with the FDA very frequently. We would interact with them, keep them updated on our product, on our surveillance of the products on the market, and the clinical outcomes, as well as the submissions for our new products.
09:26:47 Q And over the course of the years did you have conversations with the FDA about Bard's inferior vena cava filters?
A Yes, I did.
Q Ms. O'Quinn, where did you grow up?
09:26:59 A I grew up in southern Virginia in a small town called

09:27:04 Richlands.
Q And where do you live now?
A I live in Phoenix.
Q And how long have you resided in Phoenix?
09:27:09 A I've been here about almost 15 years.
Q And you have worked in the medical industry for a number of years?
A Yes, I have. I started in 1992 as a research assistant, and then started in industry in '94.
09:27:27 Q By whom are you currently employed?
A I'm employed by W.L. Gore. It's also a cardiovascular medical device company that is based here in Arizona.
Q What is your position with W.L. Gore?
A My position is the -- it's called medical functions
09:27:43 leader. It's like a leader for clinical, regulatory, quality, and medical affairs.
Q And what type of work do you do for Gore in that position?
A In that position I lead all of those teams, similar to the role that I was in at Bard, conducting all the clinical
09:28:06 research, ensuring quality of the products and the manufacturing facilities. Very similar to the role that I was in at Bard.
Q Can you please describe for the jury your educational background.
09:28:17 A Yes. My educational background is I have a bachelor in

09:28:22 biology and chemistry from University of Virginia.
Q How did you end up in the medical device field?
A Originally I wanted to go to medical school, but I was working as a research assistant and really enjoyed the
09:28:37 research side and decided to work with companies to develop products and bring those to patients. And that's how I ended up.
Q Do you still work with the FDA in your current job?
A Yes, I do.
09:28:54 Q Now, while you were with Bard, did you have any involvement with the 510(k) submissions for the Recovery filter?
A Yes.
Q And what about for the G2 filter?
09:29:03 A Yes.
Q And, generally, given your position in charge of regulatory affairs, are you aware or familiar with the 510(k) process?
A Yes.
09:29:16 Q In your experience working in the field, how rigorous a process is the 510(k) application?
A The 510(k) process is rigorous. FDA does a thorough review of the data. But for vena cava filters in particular it is very rigorous. They typically require more robust
09:29:37 engineering testing and clinical data than they do for many

09:29:41 other products that go through the 510(k) process.
Q Over the years, in your experience, if the FDA had questions regarding Bard's 510(k) submissions, did they ask those questions to the company?
09:29:54 A Yes.
Q And did they do so with regard to IVC filters?
A Yes.
Q Ms. O'Quinn, are you familiar with the Society of Interventional Radiologists guidelines regarding IVC filters?
09:30:10 A Yes.
Q In what context are you familiar with those?
A We use them as a reference document. When we were developing risk assessments or in communications with the FDA, the FDA would often ask us to provide our data and
09:30:30 indicate how it compared to the outcomes in those guidelines.
Q And so did you have discussions on occasion with the FDA specifically about the SIR guidelines?
A Yes.
Q Over the course of your years at Bard, did you have
09:30:56 frequent communications with the FDA?
A Yes, we did. They were very frequent.
Q And did you have frequent communications with the FDA regarding the Recovery and the G2 filters?
A Yes.
09:31:14 Q Did your communications with the FDA ever specifically

address reports of fracture the company was receiving regarding the Recovery filter or the G2 filter?

A Yes.

Q During your time with Bard while the Recovery filter was on the market, did the company continue to constantly monitor and assess the risk/benefit of the device?

A Yes, we were frequently assessing that. As new information became available, we were frequently assessing the -- whether the benefits outweighed the risk, and we were communicating those to the FDA.

Q Now, at some point did Bard decide while you were there to develop a second generation retrievable filter which ultimately became the G2?

A Yes.

Q And what was the express goals in developing the G2 filter?

A We were looking at improving migration resistance and fracture resistance.

Q And, generally, how did the company proceed to try to achieve those goals?

A They would frequently have conversations with physicians to seek input. They would do robust engineering testing to evaluate potential new designs. And then those that were promising, those were the ones that we would move forward for further development.

09:32:52 Q Do you recall when the company began the development process for the G2 filter?
A I don't recall the exact date, but there was a continuous process. When one product would get approved, we would
09:33:07 immediately start development of the next generation. So it was around the time that the Recovery filter was approved.
Q Did Bard ultimately seek FDA clearance for the G2 filter?
A Yes.
Q And were you involved in that process?
09:33:25 A Yes.
MR. NORTH: If we could bring up Exhibit 5349, please.
BY MR. NORTH:
Q Do you recognize 5349?
09:33:45 A Yes, I do.
Q What is this?
A That's the Special 510(k) for the Recovery filter system.
MR. NORTH: If we could look at the next page, please.
09:33:55 BY MR. NORTH:
Q This is signed by Karen Hutchison. Can you tell me who that is?
A Yes. Karen was on my team. She was a regulatory specialist that was part of my team.
09:34:12 MR. NORTH: Your Honor, I don't believe this was

admitted yesterday, so we would tender 5349.

MR. O'CONNOR: No objection subject to the agreement, Your Honor.

THE COURT: All right. 5349 is admitted.

(Exhibit 5349 admitted.)

MR. NORTH: May we display the second page, Your Honor?

THE COURT: Yes.

BY MR. NORTH:

Q And is this the letter we just referenced that Ms. Hutchison submitted as a cover letter with the 510(k) application?

A Yes.

Q Now, were you personally involved in any way in the development of this 510(k) application for the G2?

A Yes.

Q And did you actually assist in preparing or drafting portions of it?

A I did. And also reviewed and edited the portions that Karen prepared.

MR. NORTH: If we could turn to page 4 of the document, please.

BY MR. NORTH:

Q The initial submission was dated March 2 of 2005; correct?

A Yes.

09:35:15 MR. NORTH: And then if we could turn to page 20.
BY MR. NORTH:
Q As a part of the 510(k) submission did Bard provide the FDA with a description of the device?
09:35:28 A Yes.
Q And what did Bard tell the FDA was the intent or purpose in redesigning the Recovery filter for a second generation filter?
A It was to increase the migration resistance and reduction
09:35:53 of the filter arm fractures.
MR. NORTH: Could we turn to page 23, please.
BY MR. NORTH:
Q In the 510(k) submission, did Bard provide the FDA with a detailed explanation of the design changes that were being
09:36:10 made for the G2 filter?
A Yes.
MR. NORTH: Could we look at page 27, please.
BY MR. NORTH:
Q What is the risk analysis section of the 510(k) submission
09:36:28 intended to address?
A And that -- that section is an analysis of the types of risk that have been identified that could be expected with this type of product.
Q And it references a DFMEA. Do you know what that is?
09:36:53 A Yes. It's -- I think it's a design failure modes and

09:36:56 effects analysis.
Q And what sort of analysis does that consist of?
A That is an analysis based upon the design of the device, what are the types of risks that you might expect, and you
09:37:13 make estimates of what the potential occurrence rates and what the severity of the outcomes might be, and then make an assessment of whether the benefits of the device outweigh those risks.
MR. NORTH: If we could turn to page 30, please.
09:37:35 BY MR. NORTH:
Q Did Bard provide the FDA with a summary of the DV&V testing?
A Yes.
Q And what is DV&V?
09:37:45 A A design verification and validation.
MR. NORTH: If we could turn to page 36, please.
BY MR. NORTH:
Q Did Bard provide the FDA with a description of and discussion of the animal studies that had been performed?
09:38:05 A Yes.
MR. NORTH: Page 52, please.
And then could we look at page 53.
BY MR. NORTH:
Q As a part of the 510(k) submission, did Bard actually
09:38:23 provide a draft label or instructions for use to the FDA?

09:38:27 A Yes.
Q Now, even though we've identified this as the G2 submission, this labeling says Recovery filter system.
Do you see that?
09:38:37 A Yes.
Q Do you know why the discrepancy exists?
A Yes. Originally it was filed as Recovery filter, and the FDA asked us to do some additional clinical evaluation work and the -- originally the Recovery filter had a retrievable
09:38:55 indication. So when we did the additional clinical work to get the retrievable indication for G2, they asked us to change the name to G2. Or change the name and we selected G2.
Q Was that standard practice for Bard to provide a copy of
09:39:12 the proposed instructions for use to the FDA as a part of the 510(k) submission?
A Yes.
Q And on occasion did you receive comments, questions, or proposed changes from the FDA regarding the labeling or
09:39:26 instructions for use?
A Yes.
MR. NORTH: If we could turn to page 58, please.
BY MR. NORTH:
Q As a part of the 510(k) submission, does Bard also tell
09:39:45 the FDA how it intends to promote the device to the medical

community?
A Yes.
Q And is this the statements that the company submitted to the FDA that it intended to make as promotional claims with regard to the G2 filter?
A Yes.
Q Do you recall the FDA questioning those promotional statements at all?
A I don't recall any questions specific to those.
And just to clarify, they asked questions, but not specific to the promotional statement.
Q Now, there has been a suggestion in this case, or some testimony in this case, about Bard having changed the G2 migration acceptance criteria with regard to submission of the 510(k) to the FDA. Do you recall that?
A Yes.
Q Now, do you, from your personal experience, know what was said to the FDA regarding the G2 migration resistance acceptance criteria?
A Yes. There was a footnote on a table in the 510(k) where we specifically told the FDA the rationale for making that change.
Q And why did you provide that information to the FDA?
A In order to make sure they were clear on the justification for us making that change.

09:41:28 MR. NORTH: If we could look at 5349, page 30.

BY MR. NORTH:

Q Is this the footnote you were just referencing in the G2 510(k) submission?

09:41:45 A Yes.

Q And exactly what did you explain to the FDA in this application as to how the acceptance criteria had been modified and why?

A Yes. We explained that we believe that this was a

09:42:14 product iteration to the Recovery filter and that it would have been more appropriate to use that as the acceptance criteria and that we were demonstrating that it does have significantly increased migration resistance when compared to the Recovery, the predicate device.

09:42:34 Q Did the FDA ever question or express any concern about how Bard interpreted the acceptance criteria for determining migration resistance for the G2?

A No.

Q Did the FDA ever ask you to change the acceptance criteria

09:42:57 back to its original comparison to the Simon Nitinol filter?

A No.

Q Now, after this 510(k) submission was filed with the FDA, did Bard have a meeting with the agency to discuss the G2 filter?

09:43:15 A Yes, we did.

Q And did that meeting occur in March of 2005?
A I believe that's the date, yes.
MR. NORTH: If we could look at Exhibit 5905.
BY MR. NORTH:
Q Do you recognize 5905?
A Yes, I do.
Q And what is this?
A This was the agenda that I prepared for the meeting with the FDA.
MR. NORTH: Your Honor, at this time we would offer for admission Exhibit 5905.
MR. O'CONNOR: No objection, Your Honor.
THE COURT: Admitted.
(Exhibit 5905 admitted.)
BY MR. NORTH:
Q And were you sort of the moderator or master of ceremonies of this meeting?
A Yes.
MR. NORTH: Your Honor, could we display the exhibit, please?
THE COURT: Yes, you may.
BY MR. NORTH:
Q As a part of this meeting, did you discuss with the FDA what you intended to do with the G2 under next steps?
A Yes. We talked to them about the design changes that we

were making, as well as the -- looks like we also discussed the Special 510(k), all the bench testing, and the animal testing, as well as the clinical study that we had planned.

Q Do you recall who all attended this meeting for the FDA?

A Yes. It was, in addition to myself, my colleagues, Rob Carr from engineering, also our medical officer for the company, and a couple of physicians who were frequent implanters of IVC filters.

Q Were there a number of people from the FDA in attendance?

A Yes. There was a very large number of people from the FDA who attended from various groups within the FDA.

Q Now, at this time you were discussing with the FDA the submission of a Special 510(k); correct?

A Yes.

Q And did the FDA ultimately advise you that they wanted the application to go to through a different regulatory pathway?

A They did. They asked us to change it to a traditional 510(k) for the permanent indication. And then when we completed the clinical testing, then we would file another application for the retrievable indication.

MR. NORTH: Could we pull up 5348.

BY MR. NORTH:

Q Do you recognize this particular document?

A Yes.

Q What is this?

09:46:16 A This is the 510(k) that we submitted in March of 2005.
Sorry, just a moment. Let me --
This is actually the approval letter in March of '05.
Q Well, if we could, let's look at the first paragraph of
09:46:36 this. Is this actually -- letter actually approving the
submission?
A Sorry about that.
No. This one was actually asking for additional
information.
09:46:55 MR. NORTH: Your Honor, at this time we would offer
for admission Exhibit 5348.
MR. O'CONNOR: Can we look at the entire document
here, Your Honor?
No objection.
09:47:15 THE COURT: Admitted.
(Exhibit 5348 admitted.)
MR. NORTH: Your Honor, could we display this to the
jury?
THE COURT: Yes.
09:47:28 BY MR. NORTH:
Q So after you had submitted the Special 510(k) --
MR. NORTH: Let's look at paragraph 1.
BY MR. NORTH:
Q -- did the FDA come back and ask some questions?
09:47:43 A Yes, they did. They asked a number of questions,

including about the animal studies.

MR. NORTH: If we could look at the second point, bullet point.

BY MR. NORTH:

Q What did the FDA mean when it asked you to take -- or perform a proof of concept clinical study?

A They were looking for a clinical study to show that the changes that we made to the device did not affect the retrievability of the device, and that's what they meant by the proof of concept.

Q So then did Bard work with the FDA to develop a proof of concept study?

A Yes, we did. We looked at them to get input on -- on the study protocol.

Q And was that proof of concept study, was it eventually named the EVEREST study?

A Yes.

Q And did the FDA indicate that it would require that study before it would clear the device to be retrieved in patients?

A Yes.

Q Did Bard then have any discussions with the FDA about seeking clearance for the G2 as a permanent device while that study was ongoing?

A Yes.

Q Did Bard then submit additional information to the FDA

09:49:15 seeking clearance of the device as a permanent filter?
A Yes.
MR. NORTH: If we could bring up Exhibit 5350, please.
09:49:31 I believe this one is already admitted.
THE COURTROOM DEPUTY: 5350, I do not show --
THE COURT: We do not show it as --
MR. NORTH: Okay. I'm sorry, Your Honor.
BY MR. NORTH:
09:49:47 Q What is 5350?
A These -- this is the response to the questions from FDA.
Q And if we could look at the next page.
And then the page after that.
And the page after that.
09:50:06 Did you sign the letter sending these responses to the FDA?
A Yes.
MR. NORTH: Your Honor, at this time we would offer for admission Exhibit 5350.
09:50:19 MR. O'CONNOR: No objection subject to our agreement, Your Honor.
THE COURT: Admitted.
(Exhibit 5350 admitted.)
MR. NORTH: Your Honor, could we display to the jury?
09:50:33 THE COURT: Yes.

09:50:34 MR. NORTH: If we could look at the first page of the letter.

BY MR. NORTH:

Q Looking at the second paragraph, did you in this letter 09:50:53 advise the FDA that you were answering their questions and also converting this to a regular 510(k) to seek clearance for permanent use?

A Yes.

Q What sort of information did you provide to the FDA with 09:51:15 this application? Was it similar to what you had previously provided?

A Yes.

MR. NORTH: If we could look at page 17, please.

BY MR. NORTH:

09:51:22 Q So attached with the answers to the questions was also the traditional 510(k) submission?

A Yes.

MR. NORTH: If we could turn to page 75, please.

BY MR. NORTH:

09:51:43 Q What is a truthful and accuracy statement to a 510(k)?

A That statement says that to the best of your knowledge that all of the information that you're providing to the FDA is both truthful and accurate.

Q And did you sign the truthful and accuracy statement for 09:52:03 this particular 510(k) submission?

09:52:04 A Yes.
Q And when you sign statements like this to the agency, did you take your obligation seriously?
A Very much so.
09:52:14 MR. NORTH: If we could look at page 91.
BY MR. NORTH:
Q So as a part of this submission to the FDA, did you actually submit the design verification and validation protocol for the G2 filter?
09:52:29 A Yes.
MR. NORTH: Let's turn to page 127.
BY MR. NORTH:
Q I'm sorry, the page we just looked at was the test protocol for the design verification and validation test;
09:52:50 correct?
A Correct.
MR. NORTH: Then if we could turn to page 127.
BY MR. NORTH:
Q And then did you provide the agency with the actual test
09:52:59 report? So not only the protocol, but the report?
A Yes.
MR. NORTH: Could we turn to page 148.
BY MR. NORTH:
Q Did you provide the agency with the protocol utilized for
09:53:14 animal testing?

09:53:16 A Yes.

MR. NORTH: Turn to page 158.

BY MR. NORTH:

Q Did you provide the agency with the actual animal test report?

09:53:35 And look at the next page, too, please.

A Yeah, I was going to say that looked like the protocol approval page instead of --

Q Let's go one more page.

09:53:55 A I know we provided the report, but that, I don't think --

Q I believe this is still part of the protocol, isn't it?

A I believe that's the protocol.

Q Is it your -- let's look at page 184.

A Ah. Yes. This is the report.

09:54:23 MR. NORTH: If we could look at Exhibit 5344, please.

BY MR. NORTH:

Q Do you recognize what 5344 is?

A The FDA had conducted a preliminary review of our submission and then had questions, and these are the

09:54:50 questions.

Q And is this a letter from the agency raising questions, certain questions about the 510(k) you had submitted?

A Yes.

Q And is this letter addressed to you?

09:55:04 A Yes.

09:55:05 MR. NORTH: Your Honor, at this time we would offer for admission Exhibit 5344.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

09:55:13 (Exhibit 5344 admitted.)

MR. NORTH: Could we display the document?

THE COURT: Yes.

BY MR. NORTH:

Q Do you recall receiving this letter?

09:55:22 A Yes.

Q Is it typical for the FDA to send letters like this asking follow-up questions with regard to a 510(k) submission?

A Yes.

Q Does that necessarily mean there's something wrong or

09:55:37 deficient in your initial submission?

A No. It's just -- it's routine that they conduct a preliminary review, and then they send questions asking for clarification or if there's additional information that they would like to see, but that's routine as part of the review

09:55:53 process.

MR. NORTH: Okay. If we could look at the first numbered paragraph.

BY MR. NORTH:

Q Did the FDA ask you for clarification concerning the

09:56:17 animal testing?

09:56:25 A Yes.

MR. NORTH: If we could look at the second paragraph, please.

BY MR. NORTH:

09:56:33 Q Is this where the agency specifically asked you to change the name of the device and not to call it the Recovery filter?

A Yes.

Q Did Bard respond to those questions?

A Yes, we did. And that's when we changed the name to G2.

09:57:01 Q Did you provide an explanation to the FDA concerning the animal tests?

A Yes.

MR. NORTH: And then if we could look at Exhibit 5343.

09:57:16 5343.

BY MR. NORTH:

Q Is this the letter from the FDA clearing the device?

A Yes.

MR. NORTH: Your Honor, we would offer for admission

09:57:39 5343.

THE COURT: That's already in evidence.

MR. NORTH: Thank you. Could we display it?

THE COURT: You may.

BY MR. NORTH:

09:57:52 Q Ms. Allen, was this clearance letter addressed to you

specifically?
A Yes.
Q And at that time you were the director of regulatory affairs and clinical research for the company?
A Yes.
Q And what was the date of this letter?
A August 29, 2005.
Q So as of that date, was Bard authorized to sell the G2 filter?
A Yes.
Q Now, are you aware of the fact when the G2 filter was initially cleared for marketing, the Recovery filter stayed on the market for a few additional weeks?
A Yes.
Q Can you explain to the jury why that is?
A Several of the physicians told us that they had cases that were already scheduled --
MR. O'CONNOR: Hearsay, Your Honor.
THE COURT: Sustained.
BY MR. NORTH:
Q Let me ask you this way, Ms. Allen -- I mean, Ms. O'Quinn: Had the agency -- had the agency.
Had the company received any indications that some physicians might not want to move to a new filter yet?
A Yes.

09:59:03 Q And did the company have discussions with physicians who were interested in maintaining access to the Recovery filter?
A Yes. Because the cases are -- what is routine with the filter cases is they're scheduled in advance and many of the
09:59:20 cases were already scheduled. So we needed to provide the product for those scheduled cases while we were transitioning to the G2 filter.
Q Ms. O'Quinn, yesterday the jury heard a great deal of testimony concerning additional 510(k)s submitted for the G2,
09:59:46 various variations of the G2. Are you familiar with a number of those?
A Some of them, yes.
Q And did -- in your experience, did the agency repeatedly clear the G2 for sale whenever these subsequent applications
10:00:02 were filed?
A Yes. There were at least two while I was responsible for them.
Q And did those mainly deal with the delivery systems to the G2?
10:00:17 A Yes.
Q Now, let's talk about the EVEREST clinical trial.
Over the course of your career, I believe you've been in this field for more than 20 years now?
A Yes.
10:00:31 Q You've worked on with various products?

10:00:33 A Yes.
Q For different companies; correct?
A Yes.
Q Can you just tell me approximately how many clinical
10:00:41 trials you have ever conducted for Class II devices like IVC
filters?
A On IVC filters, EVEREST was the only study that I
personally was involved in.
Q Have you been involved with clinical studies involving
10:00:58 Class III devices that require premarket approval?
A Yes, I've been involved in over 50 studies for
Class IIIs.
Q So in your experience, is it unusual to have a clinical
study for a Class II device as was performed here?
10:01:18 A Yes. It's for 510(k) devices because they're Class II,
that's a classification that generally does not require
clinical data. So it was unusual to do a full clinical study
for a Class II product.
Q Now, the EVEREST study was commenced or begun at the --
10:01:40 while you were still at Bard; correct?
A Yes.
Q But you left before the study was completed?
A That's correct.
MR. NORTH: If we could look at 5324, and I believe
10:01:51 this has already been admitted.

10:02:00 THE COURT: It has.

MR. NORTH: Could we display, Your Honor?

THE COURT: Yes.

BY MR. NORTH:

10:02:09 Q We had some testimony and discussion yesterday regarding the investigational device exemption. Was this an application that had to be made to the FDA to begin the clinical study that was EVEREST?

A Yes.

10:02:22 MR. NORTH: If we could look at the next page, please.

BY MR. NORTH:

Q Is this the cover letter with the application for the IDE that was submitted to the FDA?

10:02:35 A Yes.

Q And are you personally identified in your role as director of regulatory and clinical affairs as the contact person for the FDA regarding this study?

A Yes.

10:02:53 MR. NORTH: If we could look at the next page, please.

BY MR. NORTH:

Q And did you sign the cover letter to the FDA?

A Yes.

10:02:58 Q Generally what sort of information would be provided to

10:03:01 the agency in this sort of application to perform a clinical study?

A Generally it's similar to what you would provide in a 510(k) application. It's significant information from

10:03:14 engineering, animal testing, to support moving into the clinical study.

MR. NORTH: If we could turn to page 55, please.

BY MR. NORTH:

Q Did Bard provide the FDA with a risk benefit -- benefit

10:03:35 and risk analysis concerning the device?

A Yes.

Q What's the purpose or reasoning for doing that?

A The reason for that is that with all medical devices, there are known risks. And what's important is that you have

10:03:53 data to support that the benefits of the device outweigh those risks, and that's what that analysis is that we provide to FDA as part of the IDE application for a clinical study or as part of the 510(k) for the commercial approval.

MR. NORTH: If we could look at the next page,

10:04:13 please.

BY MR. NORTH:

Q Did the company also advise the agency of its understanding of the risks involved with IVC filters?

A Yes.

10:04:27 Q If we could look down, does that include filter fracture?

10:04:31 A Yes.
Q Toward the bottom, does that include movement or migration of the filter?
A Yes.
10:04:46 Q Up a little higher, filter embolization?
A Yes.
MR. NORTH: If we could go to the next page.
BY MR. NORTH:
Q Perforation or other acute or chronic damage of the IVC wall?
10:04:59 A Yes.
Q And so were all of these risks set forth for the agency?
A Yes.
Q And then, beneath the last risk identified, stenosis, what did the company tell the FDA about those risks?
10:05:16 A We informed the FDA that the complications that we identified, there are known risks and those could be associated with serious adverse events or require medical intervention or death, and that treatment with the study device may involve additional risks which are currently unknown, but that's the reason that we collect extensive data during the clinical study to make sure we understand what those risks are, so we continued to assess if the benefits outweigh the risk.
10:06:01 Q Once you began the EVEREST study, did Bard have an

10:06:04 obligation to provide the FDA with updates on the progress of the study?

A Yes.

MR. NORTH: If we could bring up Exhibit 5333.

10:06:12 BY MR. NORTH:

Q And what is this?

A That is an annual progress report of the status of the clinical study.

MR. NORTH: Your Honor, at this time we would offer

10:06:27 for admission Exhibit 5333.

MR. O'CONNOR: No objections subject to the agreement, Your Honor.

THE COURT: Admitted.

(Exhibit 5333 admitted.)

10:06:37 MR. NORTH: Could we display, Your Honor?

THE COURT: Yes.

MR. NORTH: Thank you.

If we could bring up page 3, please.

BY MR. NORTH:

10:06:45 Q Who signed this annual progress report to the FDA?

A Hande Tufanyazici. She was a regulatory specialist that was on my regulatory affairs team.

MR. NORTH: If we could look at page 33, please.

At the bottom. Section 3.7.

10:07:13 BY MR. NORTH:
Q Did you provide the FDA in these an annual progress reports with a summary of all adverse events observed with the patients in the EVEREST study?
10:07:24 A Yes.
MR. NORTH: If we could look at the next page, please.
BY MR. NORTH:
Q And look at the second -- the first full paragraph, "In
10:07:46 total."
Did you provide the FDA with detailed information about caudal migrations that had been observed in the study at that point?
A Yes.
10:08:00 MR. NORTH: And then if we could look at page 57, please.
BY MR. NORTH:
Q Did you provide the agency with a detailed chart showing each and every adverse event that had been observed during the
10:08:19 study?
A Yes.
Q Ms. O'Quinn, in your experience, was the -- was Bard, in your group under your direction in that time period, conservative in deciding when to report adverse events?
10:08:46 A We were very conservative. Prior to that -- around that

10:08:49 period of time there was a change in the medical device industry where, for pharmaceuticals, they collected all adverse events, but it was typical for device studies to only collect the events related to the device. But we were very
10:09:03 conservative and used the pharmaceutical model of collecting all adverse events regardless of whether they were related to the product or not.

Q Now, let's change topics and talk a little bit about caudal migration in general.

10:09:17 Are you familiar with reports of caudal migration with the G2 filter?

A Yes.

Q And what's your understanding of caudal migration, what it is?

10:09:27 A Caudal migration is when it moves downward instead of up. Which was the more typical direction that you would see. So caudal was moving away from the heart. And that was something that we observed, and when we asked physicians to review it, there was less concern about that because it
10:09:49 typically did not result in any --

MR. O'CONNOR: Objection, Your Honor --

THE WITNESS: -- clinical --

MR. O'CONNOR: -- what physicians felt or said.

THE COURT: Sustained.

BY MR. NORTH:

Q Let me ask you this: What was your understanding, based upon your research and investigation and without quoting specific doctors, what was your understanding, as someone in the medical device field, about the potential severity of caudal migration?

MR. O'CONNOR: Objection. Lack of foundation.

THE COURT: Overruled.

THE WITNESS: Okay. It was -- we monitored all of the events that occurred during our clinical study and with our commercial devices, and those caudal migrations did not result in any clinical adverse events when I was there.

BY MR. NORTH:

Q When Bard started receiving reports of caudal migrations with the G2, what did the company do?

A We -- we conducted an investigation where we looked at those events very seriously. We convened panels where we discussed it with physicians and to get input.

Q And were you on the team that investigated G2 caudal migrations?

A Yes.

Q We have heard some reference to a DFMEA, design failure modes and effects analysis. What is that generally?

A That is a tool that's typically used in the medical device industry to assess the risks associated with the

10:11:23 design of a product and make estimations of what is the severity and is any additional action needed before you can make the determination of whether the risks outweigh the -- the benefits outweigh the risks.

10:11:39 Q Now, the jury has also heard in connection with a discussion about the DFMEA the concept of threshold rates. What does that mean in this sort of analysis?

A In that sort of analysis you're typically very conservative and try to estimate what the threshold rate

10:11:59 would be so that you could take action. And that action might be to review the product and the data, but you typically set those threshold rates as very conservative so if the rate of those events exceed those thresholds, then you do further investigation.

10:12:24 Q In your experience, is it more advisable for a manufacturer such as Bard to set those thresholds high or low?

A You want those thresholds to be very low because you want to trigger that investigation early.

Q For a new device like the G2, when it was launched in

10:12:46 2005, how are the DFMEA thresholds determined?

A They're determined by a combination of experience and information that we take from reviewing literature, previous product performance, and could be also set based upon our experience in animal or engineering testing.

10:13:07 Q How was the DFMEA threshold rate for migration with regard

10:13:13 to the G2 set?
A We leveraged the SIR guidelines as a reference document and used that to inform the decision of how we set the threshold rate.
10:13:27 Q And would the -- you used the experience with the Recovery filter, the predicate device, at all in setting the threshold for the G2?
A Yes.
Q In what way?
10:13:39 A We looked at the rates that were -- that were determined for the migration with the Recovery filter. But that migration was very different than what we saw with the G2 because it was caudal migration that went to the -- towards the heart, whereas caudal migration went down towards the
10:14:00 feet, away from the heart.
Q Now, at some point in 2006 was the DFMEA threshold rate for G2 migration exceeded?
A Yes.
MR. NORTH: If we could bring up Exhibit 2248.
10:14:15 BY MR. NORTH:
Q This appears to be e-mail from Natalie Wong to you and a number of others at the company.
A Yes.
MR. NORTH: I believe this exhibit is already
10:14:29 admitted.

10:14:31 THE COURT: Yes.

MR. NORTH: Could we display it, Your Honor?

THE COURT: Yes.

BY MR. NORTH:

10:14:39 Q This e-mail is dated March 2 of 2006; correct?

A Yes.

Q And does this appear to be addressed to the team that was investigating the G2?

A Yes.

10:14:59 Q And attached to this is a PowerPoint; is that correct?

A Yes.

Q And it says PAT -- Subject: PAT presentation. What is a PAT?

A It's a product assessment team.

10:15:23 MR. NORTH: If we could turn to page 19.

Could we go to the next page.

BY MR. NORTH:

Q Do you see where it says "Unacceptable risk per FMEA Type III above threshold"?

10:15:54 A Yes.

Q What does that mean?

A That means that, as I explained with the thresholds, we set those conservative, and it means that we exceeded that threshold, therefore we needed to take additional action to

10:16:09 evaluate that prior to releasing the product.

10:16:16 Q And it points to what is called a quad level. Can you tell us what that means by quad level?
A Yeah. So in the DFMEA there's an assessment that's made of severity versus occurrence, and based upon that ranking, 10:16:49 there are four different quad levels that the -- that could be assigned. And the higher the quad level, the higher the potential for the risk.
Q And if we could look over towards the left in that chart.
Am I reading that correctly that there, under number 10:17:12 of complaints, that at the time this analysis was performed, there had been 13 reports of caudal migration with the G2 filter?
A Yes.
Q And so did the company take action to investigate based on 10:17:32 only 13 events?
A Yes.
Q Do you recall what further action the company took based upon those -- that finding with 13 events to investigate the matter?
10:17:52 A Yes. That's when we assembled the product assessment team that involved a cross-functional group of people with engineers and clinical and our quality group and we assessed that information. We also convened physician panels and conducted reviews with physicians to get input.
10:18:16 Q Did you convene a meeting in Chicago of leading

10:18:19 interventional radiologists throughout the country to discuss the clinical significance of caudal migration?

A Yes.

Q You have -- we've seen the references to a physician by the name of Dr. Anthony Venbrux. Do you know him?

10:18:31 A Yes.

Q Tell us who he is.

A He is a very well-regarded interventional radiologist that implants a lot of IVC filters. He was practicing in the Washington, D.C. area at the time, I believe at Georgetown University, and he's very active in the Society of Interventional Radiology and is well-regarded as an expert in IVC filters.

10:18:51

Q And as part of the company's investigation into these 13 reports of caudal migration, did you invite Dr. Venbrux to come out to Bard Peripheral here in Tempe to assist you?

10:19:08

A Yes.

Q And what role did he play when he came out here to work with you?

A We pulled all of the information that we had available, including the imaging for these cases, and I personally sat with him and reviewed each of the cases and the imaging associated with them.

10:19:23

Q Now, to your knowledge, did Bard share with the FDA the fact that its only internal DFMEA threshold for migration had

10:19:41

been exceeded by these 13 events?

A Yes.

MR. NORTH: Could we pull up Exhibit 5881.

BY MR. NORTH:

Q What is this?

A So whenever an event occurs with a device that's currently marketed, the manufacturer has to do an evaluation and we report those events to the FDA. And when we report those events, frequently the FDA will ask for additional information. And in this instance they did, and this was our response to that request.

MR. NORTH: If we could look at the second page, please.

BY MR. NORTH:

Q This is signed by Cynthia Walcott. Do you know Ms. Walcott?

A Yes.

Q Or did you know Ms. Walcott?

A Yes.

Q And what was her position?

A She was the person that was leading the group that did these reports to the FDA and the responses to requests for additional information.

MR. NORTH: Your Honor, at this time we would offer for admission Exhibit 5881.

10:21:17 MR. O'CONNOR: Subject to the agreement, no objection.

THE COURT: Admitted.

(Exhibit 5881 admitted.)

10:21:20 MR. NORTH: Could we display it to the jury, Your Honor?

THE COURT: Yes.

BY MR. NORTH:

Q Now, when the clinical assurance personnel, such as 10:21:30 Ms. Walcott, would respond to the FDA, would your group or function of the regulatory group be involved at all in crafting or reviewing these responses?

A Yes.

Q Why is that?

10:21:44 A And that was because her group was the group that would collect all the information and evaluate the data coming in, but the regulatory affairs group was the group that was really responsible for crafting the responses to the FDA. So any time that they were -- Cindi and her team was responding 10:22:06 with more extensive information other than just a clarification, she would routinely ask the regulatory group to review it and edit it.

MR. NORTH: Now, if we could turn to the second page and question number 4.

BY MR. NORTH:

Q Does it appear that the agency had asked Bard with regard to this caudal migration event to state the expected and observed frequency and severity of occurrence for the reported incident?

A Yes.

Q And what did Bard tell the agency in response to that question?

A That the actual rate of the occurrence exceeded the expected rate and that we reassessed the DFMEA.

Q And why did it -- why had -- as a part of this product assessment team, why had the company reassessed the DFMEA?

A Because the rate of migration was higher than expected based on those threshold rates, but then when we evaluated it we found that there was a difference in that the rate of cephalad migration was much lower, but caudal migration was the reason that it had exceeded that rate.

Q So were the -- was the rate of cephalad or migration to the heart within the acceptable threshold limits in this analysis?

A The overall rate had exceeded.

Q But that would include caudal and cephalad?

A Yes.

Q And so after telling the FDA that -- well, let me back up.

And this -- when you're telling the FDA that the

10:24:04 actual rate of occurrence exceeds the expected rate, are you essentially telling them the same thing that Ms. Wong put in that PowerPoint we saw just a moment ago that the rate was unacceptable?

10:24:17 A Yes.

Q Initially based on those 13 events?

A Yes.

Q Once you told the FDA that based on this product assessment team, this panel convened with folks in -- doctors

10:24:32 in Chicago, Dr. Venbrux's review of all of the caudal migrations tests, after you had done all that and reassessed the threshold, once you told the FDA that, did they ever complain, question, or say anything about that?

A No.

10:24:57 MR. NORTH: Could we look at Exhibit 5879, please.

BY MR. NORTH:

Q Do you recognize this letter?

A Yes.

MR. NORTH: And could we look at the next page,

10:25:26 please.

BY MR. NORTH:

Q Was this again submitted by Ms. Walcott in response to an inquiry from the FDA?

A Yes.

10:25:33 MR. NORTH: Your Honor, at this time we would offer

for admission 5879.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit 5879 admitted.)

MR. NORTH: May we display, Your Honor?

THE COURT: Yes.

MR. NORTH: If we could look at question number 4.

BY MR. NORTH:

Q In this letter were you responding to another inquiry from the FDA asking you to state the expected and observed frequency and severity of occurrence for the reported incident?

A Yes.

Q And did this involve a caudal migration?

A Yes.

Q And, again, midway through the first paragraph, the sentence beginning "as the actual rate," did you -- Ms. Walcott, once again, advise the FDA that in the initial assessment of the those 13 events that triggered that unacceptable finding, that that had occurred and that the level had been reassessed?

A Yes.

MR. NORTH: And if we could look at the second paragraph on the same page, first page. I'm sorry, BPV.

10:27:02 BY MR. NORTH:
Q Did you also advise the FDA that you had established a low internal threshold initially for migration?
A Yes.
10:27:19 Q And was the reason you had done that because of the concern with cephalad migration to the heart?
A Yes.
Q Again, in this letter dated April 11th, 2006, once Bard advised the FDA that initially the level of caudal migrations
10:27:37 exceeded the DFMEA threshold, did the FDA ever express concern or any questions to the company about that?
A No.
MR. O'CONNOR: Well, objection, Your Honor. I think we need some foundation for that last question and answer as
10:28:04 to when this witness left Bard in terms of what Bard ever did.
THE COURT: Why don't you clarify that in your questioning.
BY MR. NORTH:
Q This letter was dated April 11th, 2006; correct?
10:28:19 A Yes.
Q And I believe the previous letter we saw that -- where the same information was provided to the FDA was also in 2006; correct?
A Yes.
10:28:28 Q And you remained the director of regulatory and clinical

affairs for the company into 2007; correct?

A Yes.

Q And in the almost year -- do you recall when you left in 2007?

A I don't recall the exact date, I'm sorry.

Q Well, let's just say in that eight months to a year or so that you remained with the company after this information had been provided, did you ever receive any word from the FDA in any form that they were concerned about this reassessment of the threshold after the initial finding with the 13 events?

A No.

THE COURT: We're going to break at this point, Mr. North.

MR. NORTH: Thank you, Your Honor.

THE COURT: Ladies and gentlemen, we will resume at 10:45.

(Recess taken from 10:30 to 10:45. Proceedings resumed in open court with the jury present.)

THE COURT: Thank you. Please be seated.

You may continue, Mr. North.

MR. NORTH: Thank you, Your Honor.

Could we pull up Exhibit 5880.

BY MR. NORTH:

Q Ms. O'Quinn, this letter is another letter to the FDA in response to questions about an adverse event report; correct?

10:47:09 A Yes.

MR. NORTH: And if we could look at the second page. Third page.

BY MR. NORTH:

10:47:16 Q Was this also signed by Ms. Walcott?

A Yes.

Q And, again, would you and your department have input into what was said to the FDA?

A Yes, we routinely did.

10:47:32 MR. NORTH: Your Honor, at this time we offer for admission Exhibit 5880.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit 5880 admitted.)

10:47:39 BY MR. NORTH:

Q And what is the date of this letter?

A May 11, 2006.

Q So would this have been at least seven months, if not a year, before you left the company?

10:47:50 A Yes.

MR. NORTH: If we could turn to page 2. The second paragraph and the third paragraphs.

BY MR. NORTH:

Q Once again, in response to the FDA's inquiry, did Bard

10:48:08 tell the FDA that in its initial assessment the rate of

occurrence for caudal migration exceeded the expected rate?
A Yes.
Q Did the company once again tell the FDA that the specific failure mode was reassessed in the DFMEA?
A Yes.
MR. NORTH: Your Honor, could we publish to the jury, please?
THE COURT: Yes.
BY MR. NORTH:
Q Is this basically the same disclosure that had been made to the FDA about the initial DFMEA that we saw in the previous two letters?
A Yes.
Q And, again, once this letter was sent to the FDA in response to the agency's questions, during the months, if not a year, you were with the company after that, did you ever receive any indication or questions from the FDA indicating concern about how Bard had reassessed the DFMEA?
A No.
Q What is a Health Hazard Evaluation in the medical device industry?
A That is a common document that's used to evaluate a potential risk or type of risk, and you do a very thorough evaluation of that potential hazard or risk.
MR. NORTH: If we could bring up Exhibit 5970,

10:49:41 please.
BY MR. NORTH:
Q Do you recognize this document?
A Yes.
10:49:53 Q What is it?
A This is the Health Hazard Evaluation that was done by Dr. Ciavarella. He was the medical director at that time at Bard and it was regarding the G2 vena cava filter with regard to migration.
10:50:13 MR. NORTH: Your Honor, at this time we offer for admission Exhibit 5970.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit 5970 admitted.)
10:50:21 MR. NORTH: Could we publish, Your Honor?
THE COURT: Yes.
MR. NORTH: If we could look under Description of the Problem.
And then could you highlight the date right above
10:50:35 there. You can still see it.
THE WITNESS: February 2006.
BY MR. NORTH:
Q So as of the date of this evaluation, does this indicate how many reports of migration Bard had received?
10:50:53 A Yes. Ten reports of migration.

10:50:56 Q And at that point how many filters had been sold?
A 6,200.
Q Was it unusual for Bard to launch such an extensive investigation based upon ten adverse event reports?
10:51:13 A Yes.
Q Was this Health Hazard Evaluation produced as part of the product assessment team's work that we talked about earlier?
A Yes.
MR. NORTH: If we could look at Exhibit 5539, please.
10:51:38 BY MR. NORTH:
Q What is a Failure Investigation Report?
A That is a document that was routinely prepared when we were doing investigations like that for caudal migration with the G2 filter, and it was an extensive report that was
10:51:59 prepared that included reference to many of the documents, like the DFMEA, the PAT meeting minutes, and details of any investigations or physician input that would be collected as part of the thorough investigation.
Q And did you actually sign off on this particular report?
10:52:24 A Yes. In July of '06.
MR. NORTH: Your Honor, at this time we would offer Exhibit 5539.
MR. O'CONNOR: No objection, Your Honor.
THE COURT: Admitted.
09:25:03 (Exhibit 5539 admitted.)

MR. NORTH: Could we display, Your Honor?

THE COURT: You may.

BY MR. NORTH:

Q Does this display your signature we just mentioned as one of the approvals of the Failure Investigation Report?

A Yes.

Q Would this report have been prepared with some direct input from you?

A Yes.

MR. NORTH: Let's turn to page 5, if we could.

BY MR. NORTH:

Q At the bottom it indicates root cause of failure. Did the company investigate what the root cause of the caudal migrations were?

A Yes.

Q Here it starts a sentence, "Then, expert opinion was obtained."

A Yes. From Dr. Venbrux.

Q Is this what you described earlier where you sat in a room with him and he went through the imaging you had of all reports of caudal migration?

A Yes.

MR. NORTH: If we could turn to page 7.

BY MR. NORTH:

Q Does this indicate Dr. Venbrux's assessment of what had

happened in each of these specific complaints?

A Yes.

MR. NORTH: And then if we could look at Page 8, please.

BY MR. NORTH:

Q It indicates that as the company received these reports of caudal migration, it performed a clot-trapping efficiency study.

Do you see that?

A Yes.

Q And why was the decision made to do that?

A Because there were some reports of filters that were tilting and we wanted to make sure that even if the filter tilted, it was still efficient in capturing clots.

Q And what did the test ultimately demonstrate?

A That the G2 filter is a statistically equivalent or better than the 15-degree tilted Greenfield filter, and the G2 -- and that the G2 filter was essentially still effective in capturing clots.

MR. NORTH: Then if we could look back to page 8, the whole page.

BY MR. NORTH:

Q Down at 6.4 does it reference the physician panel that you talked about earlier?

A Yes. In Chicago.

10:55:36 MR. NORTH: If we could bring up Exhibit 5537, please.

BY MR. NORTH:

Q And do you recognize what this is?

10:55:48 A Yes. I believe this is the PowerPoint presentation that we presented at that meeting.

Q And did you attend that meeting?

A Yes.

Q Did you have input into the content of this PowerPoint

10:55:59 presentation?

A Yes.

MR. NORTH: Your Honor, at this time we offer for admission Exhibit 5537.

MR. O'CONNOR: No objection.

10:56:10 THE COURT: Admitted.

(Exhibit 5537 admitted.)

MR. NORTH: May we display, Your Honor?

THE COURT: Yes.

MR. NORTH: If we could turn to page 2, please.

10:56:19 BY MR. NORTH:

Q Does this list the physicians who attended this meeting?

A Yes.

MR. NORTH: If we could go to the next slide, please.

BY MR. NORTH:

10:56:38 Q Does this list the people from Bard who attended?

10:56:42 A Yes.

MR. NORTH: Could we turn to page 12, please.

BY MR. NORTH:

Q Did the company discuss with the physician panel the

10:56:59 evidence of filter performance and complications?

A Yes.

MR. NORTH: If we could turn to 14, please.

BY MR. NORTH:

Q At this point, had the company had 14 reports of caudal

10:57:13 migration?

A Yes.

Q Were those discussed with the physicians at the meeting?

A Yes.

MR. NORTH: If we could look at 16.

10:57:23 BY MR. NORTH:

Q Did the company further explain to the physicians how many of the caudal migration incidents were symptomatic versus asymptomatic?

A Yes.

10:57:38 MR. NORTH: And then looking at page 27.

BY MR. NORTH:

Q Did Bard provide the physicians with its own calculation internally of complication rates in how -- showing the G2 filter rate based on sales at the right-hand column?

10:58:00 A Yes.

10:58:04 Q And did the company also show the physicians or point out how those compared to the SIR guidelines?
A Yes.
Q And at the time this study was done or this presentation
10:58:21 and panel was convened, had there been 12,000 G2s sold?
A Yes.
Q Had there been 14 reports of caudal migration at that point?
A Yes.
10:58:47 Q What is a quality management board review?
A That's when a group of the executive management or leadership of the company would get together and review the output of a failure investigation.
Q As the director of regulatory and clinical affairs, were
10:59:09 you a member of the management board?
A Yes.
MR. NORTH: If we could look at Exhibit 5946.
If we could look at the second page, please.
Third page.
10:59:25 We seem to only have the cover page, so why don't we go to the next one on that.
BY MR. NORTH:
Q Did the company continue to analyze caudal migration reports during the entire time that you were with the company?
10:59:47 A Yes.

10:59:49 Q Did it continue to monitor all complication reports with regard to its filters?

A Yes, sir.

Q Is that something the company did with regard to all of

10:59:58 its products?

A Yes.

MR. NORTH: Let's look at Exhibit 5967, please.

BY MR. NORTH:

Q This appears to be a risk/benefit analysis. Have you seen

11:00:19 this before?

A Yes.

Q And was this performed regarding the G2 filter in response to the reports of caudal migration? Looking under the Discussion in the second paragraph.

11:00:50 MR. O'CONNOR: I apologize, can we see the date of this document? I didn't catch that.

MR. NORTH: I'm not sure where it's displayed.

Could you go to the next page and see if we can tell.

Or maybe the last page.

11:01:07 I don't believe it bears a date.

MR. O'CONNOR: Pardon me?

MR. NORTH: I don't think I can see a date.

Can we go back to the first page, please.

BY MR. NORTH:

11:01:16 Q Was this -- can you tell under the discussion whether this

was prepared in response or -- yes, in response to the Failure Investigation Report that had been conducted regarding caudal migration?

A Yes.

Q And would you have had input into this risk/benefit analysis?

A Yes.

MR. NORTH: Your Honor, at this time we offer Exhibit 5967.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit 5967 admitted.)

MR. NORTH: Could we display, Your Honor?

THE COURT: Yes.

MR. NORTH: Could we highlight, please, under Discussion what -- how this document was created: "This document was created in response."

BY MR. NORTH:

Q And could you explain to the jury why this would have been done as an outgrowth of the Failure Investigation Report.

A Yes. During the time of the failure investigation, we identified that there was a difference in cephalad migration and caudal migration, and in order to be able to accurately assess those events we agreed that they should be broken out into two categories so they could be more closely monitored.

11:02:42 MR. NORTH: If we could turn to page 3, please.

BY MR. NORTH:

Q What was the conclusion of the risk/benefit analysis?

A The conclusion was that the benefits outweighed the risk

11:03:00 based upon the characteristics of the device.

Q Now, does Bard have a process in place to determine whether complication rates are acceptable or whether remedial action was required?

A Yes.

11:03:20 MR. NORTH: Could we look at Exhibit 5565, please.

BY MR. NORTH:

Q Do you recognize 5565?

A Yes. This is the procedure that Bard used for guiding you on how to conduct a remedial action.

11:03:42 MR. NORTH: Your Honor, at this time I offer for admission Exhibit 5565, please.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit 5565 admitted.)

11:03:56 MR. NORTH: If we could look at page 18.

If we could display, too, Your Honor?

THE COURT: You may.

MR. NORTH: Page 18, please.

BY MR. NORTH:

11:04:09 Q Down toward the bottom, does this policy and procedure

11:04:12 contain a hazard risk assessment matrix utilized by the company?

A Yes.

Q What is the purpose of that matrix?

11:04:23 A That matrix is intended to help with the assessment of risk based upon an assessment of the frequency of the event versus the severity of the event.

Q Ms. O'Quinn, as we discussed earlier, you worked personally with the FDA on the initial 510(k) to obtain

11:04:47 clearance for the G2 filter; correct?

A Yes.

Q And we talked about the term clearance. There's a distinction between clearance of a Class II device and approval of a Class III device; correct?

11:05:01 A Yes.

Q And what's the appropriate terminology for a 510(k) device?

A It's clearance. I sometimes make the mistake of saying approval because for the last three years I've been working

11:05:13 with PMA Class III devices where the proper terminology is clearance of a Class II 510(k) and approval of a PMA or Class III device.

Q So you worked personally in obtaining clearance with the agency for the 510(k) for the G2?

11:05:31 A Yes, that's correct.

11:05:33 Q And you also worked to gain, and I guess that would be approval, for the protocol for the EVEREST study; is that correct?

A Yes.

11:05:44 Q And you submitted to the FDA, or your company did with your input, a number of letters explaining the caudal migration reports regarding the G2 filters and how the company had analyzed that; correct?

A Yes.

11:05:59 Q And did you also provide information to the FDA concerning the EVEREST study and the adverse events seen in the EVEREST study?

A Yes.

Q Did you have communications with the FDA over the years

11:06:14 about these reports and these events?

A Yes. Frequent communications.

Q At any time when you were working at Bard Peripheral Vascular and during any of these communications, did the FDA ever suggest to Bard that the company should recall any of its

11:06:32 filter products?

MR. O'CONNOR: Objection. Calls for hearsay.

THE COURT: Overruled.

THE WITNESS: No.

MR. NORTH: Thank you, Ms. O'Quinn.

11:06:41 That's all the questions I have.

11:06:43 THE COURT: Cross-examination?

MR. O'CONNOR: I have a quick housekeeping matter. Can I bring it up to the side, Your Honor?

THE COURT: Yes.

11:06:48 Ladies and gentlemen, if you want to stand up, you can.

(Bench conference as follows:)

MR. O'CONNOR: I want to show her this exhibit, but Dr. Kinney's name is not redacted. But my understanding is,

11:07:10 is Dr. Kinney is not going to testify in this trial.

MR. NORTH: Right.

MR. O'CONNOR: Are we okay with that?

MR. NORTH: Yeah. We're fine.

THE COURT: Okay. Thanks.

11:07:18 (Bench conference concludes.)

THE COURT: Thank you, ladies and gentlemen.

C R O S S - E X A M I N A T I O N

BY MR. O'CONNOR:

Q Hi, Ms. O'Quinn. I'm Mark O'Connor.

11:07:46 A Hello.

Q How are you today?

A Good.

Q Thanks for coming down.

Ms. O'Quinn, you left Bard in 2007; correct?

11:07:52 A Yes.

11:07:53 Q You testified that during your time there you worked with regulatory affairs and clinical?

A Yes.

Q You do agree that the 510(k) process and the FDA relies on

11:08:09 an honor system; correct?

A Yes.

Q The FDA relies on and expects that companies like Bard will be truthful, accurate, and provide all the material information when they submit the application; correct?

11:08:19 A Yes.

Q Because what the FDA often does is looks at the paper you submit and they have to rely on what you've given them is truthful and accurate. Fair?

A Yes.

11:08:33 Q And if that rule is violated, that could mean a product that's not safe for patients could get on the market. True?

A Yes.

Q The honor system, you agree, is a very important responsibility a medical device company has. True?

11:08:48 A Absolutely.

Q And a medical device company should always put patient safety first. True?

A Of course.

Q Thank you.

11:09:06 Now, you do not know how many adverse events or

11:09:12 complaints regarding either the Recovery or the G2 came to Bard after you left. Is that fair?

A After I left. That's correct. I'm not aware of what occurred after I left.

11:09:23 Q And what you do know is that by the time you left in 2007, there were patients out there that had Recovery filters and who had G2 filters; correct?

A Yes.

Q And when you talk about other responsibilities, Bard's

11:09:41 responsibility for safety of patients doesn't stop the day the filter is sold or put in a patient, does it?

A No.

Q It has the responsibility for postmarket surveillance; correct?

11:09:54 A Yes.

Q And what that includes is receiving and reviewing complaints about adverse events; correct?

A Yes.

Q And the FDA, again, expects and relies that Bard will

11:10:07 fulfill that duty completely, honestly, and accurately; right?

A Yes.

Q And Bard, with that information, is required to track and trend adverse events that it receives. True?

A Yes.

11:10:21 Q And Bard, when it receives complaints, has obligations on

characterizing those complaints in terms of the nature of the complaints: Serious injury, malfunction. Is that fair?

A Yes.

Q That's a very serious responsibility. True?

A Yes.

Q Because that will give both Bard and the FDA, and the public, information about what trends are happening with filters; correct?

A Yes.

Q So, for example, if a G2 fractured in a patient, it's important that people at Bard, when they receive that complaint, to accurately characterize it as either a serious -- if it's a serious injury to indicate so. True?

A Yes.

Q And failure to do so could place patients who have these filters at risk; correct?

A Yes.

Q In other words, it's important for Bard to communicate with both the FDA and continue to warn doctors about trends it's seeing regarding its filters; correct?

A Yes.

Q Now, you had talked about the 510(k) process involving the G2 and the change that occurred.

A Yes.

Q And the Simon Nitinol filter, the permanent filter,

11:11:30 actually exceeded, had a higher migration resistance finding than the Recovery and G2; correct?

A Yes.

Q And so when the G2 wasn't matching with the Simon Nitinol

11:11:44 filter, the change was made so the Recovery would be the predicate device for the G2. Is that fair?

A It was changed because the G2 was an extension of the Recovery filter.

Q But you talked about migration resistance and that was one

11:12:00 of the reasons; correct?

A Well, the reason we changed it was because the more appropriate predicate was the Recovery filter, not the Simon Nitinol, because they were different designs.

Q I understand that. But I'm putting it in context.

11:12:13 We were discussing the difference in the migration resistance test results for the Simon Nitinol versus Recovery. Do you recall that testimony?

A Yes.

Q Now, you talked about cephalad migration and caudal

11:12:29 migration. Cephalad migration is migration that goes up towards the heart; right?

A Um-hmm. Yes.

Q And caudal migration is migration that goes downward; correct?

11:12:41 A Yes.

11:12:42 Q And when the G2 was developed, your goal at Bard was to improve resistance for cephalad migration; correct?
A Yes.
Q Because that was the problem with the Recovery, wasn't it,
11:12:57 cephalad migration, among other things?
A Yes.
Q And the cephalad migration in the Recovery was causing serious health consequences to patients. True?
A There were serious events, yes.
11:13:10 Q And you talked about doctors when the Recovery was going to be taken off the market, there were some doctors you believed still wanted it; correct?
A Yes.
Q But you don't know what any of those doctors knew about
11:13:26 the events concerning the Recovery. Fair?
A Events were -- risks were routinely communicated via product labeling and Bard had communications with physicians about the events.
Q I'm talking about actual incidents, complaints. You don't
11:13:45 know what physicians knew that Bard was receiving in terms of complaints or adverse reports regarding cephalad migration. Is that fair?
A I know what we communicated to them. I can't speak to an individual physician, but I know what we were communicating
11:14:00 about the product.

11:14:01 Q I understand that. But just so you and I are on the same page, you don't know what individual doctors knew or did not know about the experience with the Recovery in terms of total events that were causing serious health consequences. True?

11:14:13 A I can only speak to what we communicated.

Q Okay. And the sales force too. The sales force was the eyes and ears of Bard; correct?

A Yes.

Q So they -- doctors relied on your sales force to

11:14:30 communicate accurate information to them. Fair?

A Yes.

Q But the sales force could only communicate to doctors what information it had received from Bard. Fair?

A Yes.

11:14:42 Q So if there was tracking and trending at Bard regarding serious health consequences caused by the cephalad migration in the Recovery, if that wasn't given to sales, sales would not necessarily know, would they?

A If they didn't receive it, they wouldn't know.

11:14:59 Q And it would make sense if sales didn't know the extent of serious health consequences from the Recovery, they wouldn't be able to effectively communicate that to the doctors. You agree with that?

A But that's a hypothetical situation.

11:15:13 Q You agree with me?

11:15:14 A If we didn't communicate it, yes, they wouldn't have a way of knowing.

Q Thank you.

Now, I want to talk to you about this meeting in 11:15:24 Chicago on June 1, 2006.

MR. O'CONNOR: Gay, could you please put up Exhibit 5536.

BY MR. O'CONNOR:

Q These are minutes from that meeting; correct?

11:15:40 A Yes.

MR. O'CONNOR: I move to admit 5536, Your Honor.

MR. NORTH: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 5536 admitted.)

11:15:53 MR. O'CONNOR: May we display to the jury, please?

THE COURT: Yes.

BY MR. O'CONNOR:

Q And what this meeting consisted of, Ms. O'Quinn, was actually a focus group with different doctors; correct?

11:16:03 A Yes.

Q And you received during that meeting different input from different doctors about experiences and things they would want with filters; correct?

A Yes.

11:16:18 Q So, for example --

MR. O'CONNOR: Gay, go down to IVC perforation.

BY MR. O'CONNOR:

Q And do you see the third line down. It says -- these are different doctors giving different input. One doctor said about perforation "Okay if asymptomatic, but could become symptomatic over time."

Do you see that?

A Yes.

Q And certainly that's why you folks at Bard were meeting with these doctors, to find out what their experiences were out there in the real world with filters; right?

A Yes.

MR. O'CONNOR: And then, Gay, if you could go down to Fracture.

Gay, if you could highlight "Concern expressed over potential embolization."

BY MR. O'CONNOR:

Q And some of the doctors communicated they were concerned that fractures could embolize to the lungs and cause material failure.

Do you see that?

A Yes.

Q And earlier when you were talking about different exhibits with Mr. North and you were showing what types of complications you were listing, fair to say that fracture

11:17:35 embolization was not one of the risks of complications that was included?

A Fracture and embolization was included in the risk information we shared with the FDA. So I would need you to be specific about which document --

11:17:50 Q I'm talking -- let me see if I can find that. Thank you.

MR. O'CONNOR: Gay, can you --

Let me finish this document because there's something else I wanted to talk to you about, then we'll look at the next document.

11:18:10 Gay, last bullet point under Fracture, please. "Physicians are more comfortable."

BY MR. O'CONNOR:

Q Physicians were communicating to you how serious fracture was in their minds. True?

11:18:30 A Yes.

Q As a matter of fact, they even indicated to you a physician would be more comfortable with a small PE, that is pulmonary embolism, that is asymptomatic than a fracture. True?

11:18:40 A Yes.

MR. O'CONNOR: Gay, if you could go to the next page, please.

Go under "BPV experience." First bullet point there, Gay.

11:19:02

BY MR. O'CONNOR:

Q Now, people from Bard were also participating in the focus group and relaying to the doctors in the focus group what experience at Bard was and how Bard was handling certain events. Fair?

A Yes.

Q Here it says "BPV experience should focus on symptomatic conditions" and "asymptomatic events probably occur at a much higher rate because underreported."

Did I read that correctly?

A Yes.

Q And certainly that was a concern that was addressed in the Chicago 2006 meeting; correct?

A Yes.

Q Because, as we saw earlier, if you take fracture, a fracture could occur and a patient not know he or she has any symptoms; right?

A It could be asymptomatic, yes.

Q But then it could embolize, move, and go to a place that's dangerous for that patient. True?

A Potentially.

Q Whether a patient feels it or not, it could be dangerous and life-threatening depending on where it lands; correct?

A I can't speak to that, I'm not a physician.

Q Fair enough. But that would make sense to you. True?

A There's the potential for complication, yes.
Q All right.
And the other issue that was discussed was the problem with underreporting. True?
A It was not that there was a problem with underreporting, but it was a note that if it -- if the event is asymptomatic, the patient may not be aware of it. So it could be underreported because of an unawareness.
Q And that was always a concern of yours at Bard, too, right, about we know we're receiving events that people or doctors are reporting to us by way of complaints; right?
A Yeah.
Q But you, in your position of regulatory affairs, with your interest in patient safety, also had to be concerned with how many out there that we don't know about; right?
A Yes. And in letters that we communicated to physicians we reminded them of their reporting requirements, if they were aware of it. Irregardless of whether it was asymptomatic or symptomatic.
Q Well, it's just like other diseases. Oftentimes people can have a disease and not know that they have a deadly disease; right?
A Exactly.
Q And so a patient can't report anything to the doctor if he or she doesn't know about the filter has broke or embolized.

True?
A Yes.
Q And if it's not reported to a doctor, it won't get reported to Bard; correct?
A Yes.
Q And that's a concern about underreporting. True?
A Exactly.
Q Thank you.
And so, in other words, the problem that's always been on your mind, one of them, is how many are out there that have filter complications and they just don't know; right?
A Yes.
MR. O'CONNOR: Can we see Exhibit 1221, Gay, please.
I move --
BY MR. O'CONNOR:
Q This is a Health Hazard Evaluation dated February 15, 2006.
Do you see that, Ms. O'Quinn?
A Yes.
Q This is still during the period of time you were at Bard; correct?
A Yes.
MR. O'CONNOR: I move for the admission of 1221.
THE COURT: It's already in evidence.
MR. O'CONNOR: Oh. Thank you.

11:22:40 Gay, if you could, in the Summary section, highlight "70 percent of the cases."

BY MR. O'CONNOR:

Q And, again, these are reports that come out frequently

11:22:53 that are prepared by Dr. Ciavarella, the medical director, is that right, Ms. O'Quinn?

A Yes.

MR. O'CONNOR: And, Gay, highlight that entire sentence.

11:23:04 Oh. May I publish to the jury, Your Honor?

THE COURT: Yes.

BY MR. O'CONNOR:

Q And there it says "In 70 percent of these cases the filter was found to be out of position," parens, "tilted or in

11:23:17 anatomically suboptimal position, raising questions about primary effectiveness."

Now, did I read that correctly?

A Yes.

MR. O'CONNOR: Gay, if we could go quickly to

11:23:29 Exhibit 6046.

THE WITNESS: But I want to clarify that that was the reason we did the filter clot-trapping efficiency testing.

BY MR. O'CONNOR:

Q But all I asked you was if I read what was stated in that

11:23:41 document accurately; correct?

11:23:43 A Yes.
Q All right.
Now, you were involved in the beginning of the EVEREST study; correct?
11:23:50 A Yes.
Q And that study involved 100 patients. True?
A Yes.
Q And it was going to be for retrievability; correct?
A Yes.
11:23:58 Q And it was a set period of time when those patients would be looked at to see if the filter could be retrieved. Fair?
A Yes.
Q And a medical monitor in that case was Dr. Chris Kandarpa; correct?
11:24:09 A Yes.
Q And certainly Bard would hire doctors like Dr. Kandarpa who they could rely on to accurately report findings during this study; correct?
A Yes.
11:24:17 Q One important part of the study is to have doctors there who will voice concerns to Bard about potential health complications to make sure the patients in the study are safe; right?
A Yes.
11:24:31 MR. O'CONNOR: Gay, please go to the second page.

11:24:39 And, Gay, if you could in the -- under "AE Form" there's the full paragraph as part of the clinical update. I'd like to you highlight "There were many filter tilts in the study," that whole sentence there, please.

11:25:02 BY MR. O'CONNOR:

Q Ms. O'Quinn, all I'm going to do is read this and ask you if I read it correctly. Okay?

A Okay.

THE COURT: This is not in evidence.

11:25:11 MR. O'CONNOR: Oh, I'm sorry. May I move 6046 into evidence, Your Honor?

MR. NORTH: No objection, Your Honor.

MR. O'CONNOR: May we publish?

THE COURT: Admitted. You may.

11:25:23 (Exhibit 6046 admitted.)

BY MR. O'CONNOR:

Q And we're talking about the EVEREST study and medical monitor adjudication meeting minutes that your company would receive periodically; is that right?

11:25:37 A Yes.

Q And we're looking at 6046, exhibit number.

And here's what Dr. Kan- -- what was reported by Dr. Kandarpa, and just tell me if I read this correctly: "There were many filter tilts in this study with site 07 reporting the most. Patient 09-007 had significant device

11:25:51

11:25:56 issues. Dr. Kandarpa expressed concern about the number of reported tilts hitting approximately 20 percent and thought that Bard may want to closely evaluate this."

Now, did I read that correctly?

11:26:11 A Yes, but there's a lot of context that's relevant.

Q Did I read that correctly?

A Yes.

Q All right.

And certainly Dr. Kandarpa was somebody that folks at

11:26:20 Bard trusted and relied on. True?

A Yes.

MR. O'CONNOR: Gay, go down to the next paragraph, please.

And there's a sentence there, Gay, where it says

11:26:28 "Dr. Kandarpa wanted to know."

BY MR. O'CONNOR:

Q Again, I'm going to read this. Just tell me if I read this statement correctly. "Dr. Kandarpa wanted to know if we were concerned" -- "we" being Bard -- "that almost 50 percent

11:26:50 of patients have reported AE/SAE."

Did I read that accurate -- correctly?

A You read it accurately.

Q All right. That's all I'm asking you.

AE stands for adverse event; correct?

11:27:04 A Yes, but it does not imply related to the device.

MR. O'CONNOR: I move to strike. I just asked her a yes or no question.

THE COURT: You need to clarify what kind of answer you want --

BY MR. O'CONNOR:

Q AE, the letters AE, does that stand for adverse event?

A Adverse event of any type.

Q Pardon me?

A Adverse event of any type. It doesn't have to be related to the device.

Q All right. Thank you.

SAE stands for serious adverse event. True?

A Yes.

Q Thank you.

MR. O'CONNOR: You may take that down, Gay.

BY MR. O'CONNOR:

Q And Bard, as a medical device company, must investigate complaints and report those complaints accurately to the FDA; correct?

A Yes.

Q And medical doctors rely that Bard is accurately reviewing and reporting adverse events; correct?

A Yes.

Q And if Bard doesn't, that could put the patients who receive filters from Bard at risk of harm; correct?

11:28:18 A Yes.

MR. O'CONNOR: Thank you. That's all I have.

THE COURT: Redirect?

MR. NORTH: Nothing further, Your Honor.

11:28:24 THE COURT: All right.

Thank you. You can step down.

MR. ROGERS: Defense calls its next witness, Dr. Moni Stein.

Your Honor, may I hand up a copy of his two reports?

11:29:04 THE COURT: Yes.

If you want to stand up, ladies and gentlemen, while we're getting set, you can do that.

THE COURTROOM DEPUTY: Dr. Stein, if you would come forward and raise your right hand. Stand right here, please.

11:29:15 Thank you.

MONI STEIN, M.D.,

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

THE COURTROOM DEPUTY: Could you please state your

11:29:27 name and spell it for the record, sir.

THE WITNESS: Moni Stein. M-O-N-I, S-T-E-I-N.

THE COURTROOM DEPUTY: Thank you, sir. Please have a seat.

11:29:47

D I R E C T E X A M I N A T I O N

BY MR. ROGERS:

Q Dr. Stein, could you introduce yourself to the jury, please.

11:30:03 A So I'm Dr. Moni Stein. I'm an interventional radiologist. I practice in Columbus, Ohio.

Q And, Doctor, what is going to be the focus of your testimony today?

A It's going to be the medical history of Ms. Jones and the

11:30:18 issues around the filter and the strut, so forth.

Q Doctor, can you tell us where you were born.

A I was born in Romania.

Q And are you married?

A Yes.

11:30:30 Q Do you have children?

A I have five children.

Q And what are their ages?

A They range between 17 and 24.

Q Let me ask you some questions now about your education and

11:30:44 training. Can you tell us where you went to college.

A So I went to college in Canada, university called McMaster University.

Q Where did you go to medical school?

A Medical school, University of Toronto in Toronto, Canada.

11:30:58 Q And after you finished medical school, did you do

11:31:01 additional training?
A Yes. So I stayed at University of Toronto for radiology residency. That was four years. So I was board-certified in general radiology after that, then I went to University of
11:31:18 California in San Francisco for fellowship. Was very fortunate, it was a very nice fellowship. And after that I was CAQ, Certificate for Added Qualification in interventional radiology. That required an additional exam.
Q Was your fellowship in interventional radiology?
11:31:37 A Yes, it was.
Q And have you been practicing as an interventional radiologist since that time?
A Yes.
Q And, Doctor, have you done any teaching?
11:31:45 A Yes. Absolutely. Teaching actually started in -- during the fellowship. So I taught residents interventional radiology, and then when I was at the University of California at UC Davis I was an attending there, so one of my main responsibilities was to actually teach residents and
11:32:07 fellows.
Q Did your teaching include teaching the other -- the fellows and interventional radiologists about IVC filters?
A Yes. Absolutely.
Q Did you also train those fellows in how to place IVC
11:32:23 filters?

A Yes.
Q Doctor, you told us you practice currently in Columbus, Ohio, I believe?
A Yes.
Q Are you in private practice?
A Currently I'm in private practice.
Q Can you tell the jury, please, about your practice.
A So my practice is kind of a mixture of general radiology and interventional radiology. It's about 40 percent general radiology and about 60 percent interventional radiology.

The two are a little different. General radiology is basically interpreting imaging, X-rays, CTs, MRIs, ultrasound, and producing reports. And providing some consultation to referring physicians.

Interventional radiology is more of a clinical subspecialty. You actually see patients in clinics, you do procedures, you talk to their families. It's a lot more hands-on clinical subspecialty. It's a different flavor.
Q So, Doctor, is it fair to say you both read and interpret X-rays and other imaging studies, but you also perform procedures as an interventional radiologist?
A Yes.
Q Are you in the Society of Interventional Radiology?
A Yes. I've been a member since my fellowship, so for quite a while.

Q Are you a senior fellow in the Society of Interventional Radiology?
A Yes, I am.
Q How long have you been a senior fellow?
A I'd say about 20 years.
Q Are you licensed to practice medicine?
A Yes, I am.
Q And are you board-certified?
A I am board-certified.
Q What states are you licensed to practice in?
A California and Ohio.
Q In your practice, since you were in your fellowship, have you routinely worked with IVC filters?
A Yes. Absolutely.
Q And approximately how many IVC filters do you believe that you have implanted over the course of your career?
A Approximately 600.
Q And about how many filters would you estimate that you have retrieved?
A As far as -- I implanted 300 that were retrievable and a portion of that I retrieved, I actually retrieved. But I implanted about 300 retrievable filters.
Q I see. So you've implanted both permanent and retrievable filters?
A Yes.

11:34:49 Q And earlier in your career, before retrievable filters were on the market, you implanted only permanent filters?
A Yes. That was the only thing available at that time.
Q Have you implanted and retrieved Bard IVC filters?
11:35:01 A Yes.
Q And approximately how many Bard filters do you think you have implanted?
A About half of the filters that I implanted. So about 300.
11:35:11 Q Have you implanted other IVC filters made by different manufacturers?
A Yes.
Q And would that include IVC filters that are retrievable that were made by different manufacturers?
11:35:22 A Yes.
Q And have you retrieved IVC filters made by a manufacturer other than Bard?
A Yes.
Q And, Doctor, before we get into the substance of your
11:35:34 opinion, I do want to ask you, are you charging for your time?
A Yes, I do.
Q And how have you been compensated for your work in this matter?
A When I do work, let's say at home, I get compensated $400
11:35:49 an hour. And for a trial like this, when I have to come for

11:35:55 a full day, I usually get compensated proportional to what I get paid at home. For example, those two days I was supposed to work, so in order for me to be here I had to compensate another one of my partners to take my position. So for a day 11:36:12 without call, that would be $2500, and for a day with call is an additional $500. $3,000. For those two days about $5,500.

Q So for the course of your trip out here to Phoenix from Columbus, you're going to charge about $5,500?

11:36:30 A Correct.

Q Doctor, in the course of getting ready to give your opinions in this case, did you review the medical records of Doris Jones?

A Yes, I have.

11:36:41 Q And have you also reviewed various imaging studies like X-rays and CT scans?

A Yes. Absolutely.

Q And are you prepared to offer your opinions in this case?

A Absolutely.

11:36:51 Q And are you prepared specifically to offer an opinion in this case as to whether Ms. Jones received a benefit from the Eclipse filter that was implanted in her?

A Yes.

Q And you're also prepared to offer an opinion about the

11:37:05 filter fragment that remains in her pulmonary artery?

11:37:10 A Yes.
Q Doctor, let's start with the filter itself when it was first implanted. And do you recall that her filter was first implanted in 2010?
11:37:21 A Yes.
Q And do you have an opinion as to whether Ms. Jones needed a filter at that time?
A Yeah, absolutely she needed a filter.
Q And why is that?
11:37:32 A Well, Ms. Jones had a complex medical history. She had two conditions that were difficult to manage simultaneously. One condition was gastrointestinal bleeding, life-threatening condition. She came to the emergency department multiple times with bleeding. I think one time she had to go to the
11:37:53 intensive care unit. Very serious life-threatening condition.

But then she also developed DVT, deep vein thrombosis. And I believe that happened first time in 2006 and second time in 2010. So when someone has deep vein
11:38:11 thrombosis, they're at high risk for pulmonary embolism. Another potentially life-threatening condition.

So those two conditions were together and they had to be managed together. The problem is, is that the usual management for deep vein thrombosis is blood thinners,
11:38:28 anticoagulants. And when you give somebody anticoagulant, it

promotes bleeding. So because she had the massive gastrointestinal bleeding, they could not give her the anticoagulant. So the only option for treatment at that point, in order to prevent pulmonary embolism, was to actually put the filter in. So the filter was a very, very important intervention that she absolutely needed.

So putting the filter in not only protected her against pulmonary embolism, but also allowed the surgeons to actually deal with her underlying condition, which was the gastrointestinal bleeding.

She had a giant duodenal ulcer, and the only way to deal with that was through surgery, and surgeons cannot operate while you are on blood thinners.

So the filter had, really, a dual purpose here and it did exactly what it was supposed to do.

Q And in your opinion did Mrs. Jones receive a benefit from the Eclipse filter?

A Absolutely.

Q Let's kind of shift gears and move forward a little bit, Dr. Stein, and turn our attention to April of 2015. Is that when Ms. Jones went to the ER?

A Yes, she did.

Q And do you recall what symptoms she presented with when she went to the ER?

A Yes. She had dizziness and also she complained of some

11:39:58 shoulder pain. Those are the main presentations.
Q And as part of that admission, did she receive a chest X-ray?
A Yes, she did.
11:40:07 Q And what -- what would be the reasons that doctors would order a chest X-ray for her in that situation?
A Well, you know, a chest X-ray is a very nonspecific evaluation that is ordered very frequently in the ER because she had kind of nonspecific symptoms. Dizziness is
11:40:26 considered relatively nonspecific symptom. Can be caused by cardiac issues, all sorts of issues. So a chest X-ray is good screen to see what's going on.
MR. ROGERS: Can we pull up Exhibit 8404, please.
BY MR. ROGERS:
11:40:39 Q And, Doctor, do you see Exhibit 8404 on your screen?
A Yes, I do.
MR. ROGERS: Your Honor, at this time I move Exhibit 8404 into evidence.
MR. COMBS: No objection, Your Honor.
11:41:00 THE COURT: Admitted.
(Exhibit 8404 admitted.)
MR. ROGERS: May we publish?
THE COURT: Yes.
BY MR. ROGERS:
11:41:06 Q Doctor, can you explain to the jury what we're seeing

here.
A So this is a standard well-taken chest X-ray. It is a normal chest X-ray. There's one finding in this chest X-ray that is actually pretty subtle, but the radiologist did see it. I don't know if you can see those little arrows --
Q Let me ask you this, Doctor: Would it be helpful to enlarge a section of that?
A Yes.
So you can see there is a linear fragment in there. That is the metallic fragment that embolized. And so that is the finding.
Q And the arrows that appear on the screen right now, are those arrows you put on there or are they arrows that came with the X-ray as it was provided by the hospital?
A I think it was put in there. I don't know that I put them in there, but it was added.
Q And do you know if it was by the treating radiologist?
A As I recall, the first X-ray that I reviewed did not have arrows on it, so it must have been added later. But it accurately shows what the finding is.
Q And, Doctor, what can this image that we see here tell us about the location of the strut?
A So, just to remind you, that chest X-ray is kind of two-dimensional view. So you don't really have an idea as to where this structure is, whether it's on the patient, in the

patient or in back of the patient. So basically, in order to really find out exactly where it is, you need another study which is called CT. CT scan.

Q Is that what Mrs. Jones' treating doctors ordered?

A Yes. Appropriately so.

Q Okay. So why don't we shift to that.

MR. ROGERS: Can you pull up Exhibit 8405, please. And at this time I move 8405 into evidence.

MR. COMBS: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 8405 admitted.)

MR. ROGERS: May we publish?

THE COURT: Yes.

BY MR. ROGERS:

Q And, Doctor, is this an image from the CT scan that was done on Mrs. Jones in April?

A Yes.

Q If you would, before we get into the specifics of this particular image that's on the screen, can you explain to us generally what a CT scan is?

A Yeah. CT scan is what we call a cross-sectional imaging. So the patient usually lies supine, on their back, and they go into the scanner, and the scanner scans, kind of slices through the patient, kind of across the body at an interval of 5 millimeters or 10 millimeters, it depends on what kind

of study it is. So basically it gives you a very good evaluation of the body sliced horizontal like that.

Q And so if you have a CT scan, can there be different ways that the CT scan can be sliced?

A Well, it is usually acquired in one way. It's usually through axial images. And then, in addition to that, the technologist usually, through software manipulation, they provide reconstructions so we can see the same structures either in the coronal plane, which is slicing this way, or the sagittal plane, which slices from the side.

They try to depict the same kind of information except in a different kind of a way in order to make it a little easier on the interpreting physician and referring physicians to understand exactly where it is. Especially it's very, very beneficial, let's say in surgery, because surgeons like to know the three-dimensional implications of what their target is. So it's very useful to provide those reconstructions.

Q And what type of slice is it that's on the screen? Which way?

A This is the axial one. And this is the way it's acquired, so -- this is pretty much the native way that it's acquired, so this is the most reliable way to look at it.

Q And, Doctor, if you would, I believe you can touch your screen, but can you show the jury where the strut is.

11:45:29 A So if you look at that area where the circle is, you can see that there is a vessel, and then there is a dense linear object in there. There it's parallel to the vessel and it lies against the wall of the vessel. So that's the strut 11:45:52 that we are referring to that we saw in the chest X-ray.

Q And what else can you tell us about the strut and its interaction with Mrs. Jones' artery?

A So the strut occupies probably less than 10 percent of the diameter of the vessel. You can see that the vessel is 11:46:14 bright, which means that the contrast is going through it.

This is, by the way, a CTA, CT angiogram, which means it was done in a way that contrast was injected and we can highlight the vessels. So that's really important because it gives you information about what's inside the vessel.

11:46:32 So in this particular case you can see the strut opposed to the wall. And you can see the contrast in the vessel, which means there's no clot in there.

In addition to that, the lung surrounding the structure is absolutely normal and there's no reaction 11:46:50 whatsoever. So it kind of sits there. At this time it may be endothelialized, it's hard to tell. But I consider this to be in a very stable position.

Q Do you see any evidence of any bleeding or clotting around the strut?

11:47:06 A None whatsoever.

11:47:07 Q And in your opinion, was the filter strut the cause of the symptoms that Mrs. Jones experienced when she presented to the hospital in April of 2015?

A I do not believe so. I think it would be a stretch to 11:47:24 attribute this little linear structure that has absolutely no reaction around it to attribute dizziness to that or shoulder pain to that. It just doesn't make any sense. There's no anatomic connection.

Q Doctor, do you agree with the treating doctor, Dr. Nelson, 11:47:48 with her decision to leave the strut in place?

A Couldn't agree with her more because we have a saying in our practice. That is, we do not treat X-rays, we treat patients. So in a patient like this, we know she's been through a lot. A lot of comorbidities, she's had surgeries. 11:48:14 The last thing she needs is another procedure.

And in my judgment, this is a very stable situation. And to do another procedure for her would be traumatic and potentially damaging. And in addition to that, we don't know exactly when the embolization event happened because the 11:48:35 previous chest X-ray was actually in 2013. So this event may have occurred a year before maybe. Maybe a year and a half before. Maybe six months ago.

But what could have happened is after it embolized and been there for a while, the body reacted to it. So what 11:48:53 happens is that it gets incorporated into the wall of the

artery. So when that happens, it becomes really difficult to try to take it out. You have to use invasive instruments and you have to dig inside the wall. And in doing so you may actually cause damage, bleeding. You can -- you can cause a disaster, basically.

So, again, in this particular situation where the patient was stable, in my opinion her symptoms were completely unrelated to the strut, to go after this was absolutely no reason. If it were my patient, I would definitely advise against it. Not because Dr. Nelson couldn't do it. I think she had the skill set of doing it. I think she used very, very good judgment, and I completely approve her judgment of doing so.

Q Doctor, let's move forward a little bit in time and talk about 2016. Did Mrs. Jones go to the emergency room in 2016?

A Yes, she did.

Q And what were the issues that she presented with when she went to the hospital in 2016?

A She may have had something -- I think she had gastrointestinal bleeding again.

Q Did she require additional surgery at that time?

MR. COMBS: Objection, Your Honor. Nondisclosure.

THE COURT: Is that in the report?

MR. ROGERS: I'll move on rather than look for it, Your Honor.

THE COURT: All right.

BY MR. ROGERS:

Q Let me ask you this: In 2016 was a chest X-ray ordered for Mrs. Jones?

A Yes, it was.

Q And have you reviewed that chest X-ray?

A Yes, I did.

MR. ROGERS: Can we get Exhibit 8407.

And, Your Honor, I'd move 8407 into evidence.

MR. COMBS: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 8407 admitted.)

MR. ROGERS: May we publish?

THE WITNESS: Yes.

BY MR. ROGERS:

Q Doctor, do you have that exhibit on your screen?

A Yes, I do.

Q Can you explain to the jury what you see in this X-ray.

A So this chest X-ray is very, very similar to the chest X-ray done in 2015. It is essentially a normal chest X-ray. Almost a replica of the chest X-ray in 2015. There is one additional thing here, that she has a PICC line. She has a line that comes from her right arm. You can see it kind of starting here.

But other than the PICC line, we also see the little

strut we saw before in 2015. I don't know if you want to magnify it or not, but --

Q Would it assist you to magnify that area?

A Please.

MR. ROGERS: Scott, can you do that.

THE WITNESS: So we can see the strut right here. And the strut is in exactly the same location like it was in 2015. It's pretty much identical. Has not moved an inch.

BY MR. ROGERS:

Q And between the 2015 and the 2016 X-ray, approximately how much time elapsed?

A Almost a year.

Q During this hospitalization did Mrs. Jones receive any sort of treatment regarding this strut?

A No.

MR. ROGERS: You can take that down, please.

BY MR. ROGERS:

Q And, Doctor, let me ask you generally about struts in the pulmonary artery. When that occurs and a patient has got a filter fragment in their pulmonary artery, are those events typically clinically silent?

A Yes, they are silent.

Q And have you treated patients in your practice who have had fragments of filters in their pulmonary artery?

MR. COMBS: Objection. Nondisclosure, Your Honor.

11:52:29 THE COURT: Is that in his report?

MR. ROGERS: I'll move on, Your Honor.

THE COURT: All right.

BY MR. ROGERS:

11:52:33 Q Let me ask you this, Doctor: In your practice have you purposefully implanted metallic devices in the pulmonary artery?

A Yes.

Q And can you tell the jury about that, please.

11:52:45 A Sometimes we deal with conditions like arteriovenous malformations. It's kind of a congenital thing. People are sometimes born with it. They have abnormal communication between the pulmonary artery and pulmonary vein.

When that happens, we like to block them

11:53:06 intentionally, so we actually put coils in there, metallic coils. So metallic coils material-wise are kind of similar to the structure that we saw in Ms. Jones' pulmonary artery. So there is some similarity.

Q And when you place those metallic coils in a pulmonary

11:53:24 artery for patient treatment, do those coils stay there?

A Yes.

Q Is that something that goes into the patient permanently?

A Yes.

Q And have you followed those patients that have those coils

11:53:37 over time?

11:53:38 A Yes, we do.

Q And typically do they run into any issue with having metallic coil in their pulmonary artery?

MR. COMBS: Objection. Nondisclosure.

11:53:47 THE COURT: Is that in the report?

MR. ROGERS: He does talk about metallic coils, Your Honor. And if we want to take a look at it, that's fine. It's on page 4 of the Doris Jones report, paragraph 6.

MR. COMBS: I would just add, Your Honor, he's going

11:54:02 into quite more detail about that than in his report.

THE COURT: I don't have numbered pages in this report. Is it the fourth page?

MR. ROGERS: If you start -- yes, sir. With the first page being the cover page, it's the fourth page in, and

11:54:19 it's in the sixth paragraph down.

THE COURT: What's at the top of the page?

MR. ROGERS: The top of the page says "Opinion."

THE COURT: Sixth paragraph?

MR. ROGERS: Yes, sir. They're kind of blended

11:54:31 together there.

THE COURT: All right.

MR. ROGERS: The sentence, Your Honor, is about in the middle. It says "I have placed metallic coils."

THE COURT: I see the sentence. Hold on just a

11:54:58 minute.

Objection is overruled on the question that was just asked.

BY MR. ROGERS:

Q Let me ask you again, Dr. Stein. In the patients where you have implanted metallic coils, do the coils stay in there permanently for the patients?

A Yes, they do.

Q Have you followed those patients over the course of time?

A Yes, we do.

Q And have you seen those coils cause any sort of adverse events, like blood clots or anything of that nature, in the pulmonary artery?

A Well, the coils are meant to actually block the blood vessel. But I've never seen an infection associated with those coils. Never.

Q Let me shift gears a little bit and talk to you about the medical literature.

Are you aware of any medical literature that has addressed the management of patients who have got a filter fragment in their pulmonary artery?

A Yes. So there is this article by Trerotola and his colleagues. A paper that comes --

MR. COMBS: Objection, Your Honor. Nondisclosure.

MR. ROGERS: Your Honor, page 5, paragraph 1.

MR. COMBS: Which report?

11:56:29 THE COURT: Same report.

MR. ROGERS: Jones report.

THE COURT: Objection's overruled.

BY MR. ROGERS:

11:56:34 Q You may continue, Doctor.

A So there's a paper from Dr. Scott Trerotola, who I know personally, by the way, from University of Pennsylvania. And they described fairly significant experience with embolization of fragments of IVC filters and attempted

11:56:56 retrieval. And that paper was published in the journal of Radiology, which is a pretty good journal. And that's the paper we're talking about here.

Q Was that paper published in 2017?

A Yes.

11:57:08 Q And do you know of any other medical articles in the literature that discuss the management of patients with a filter strut in their pulmonary artery?

A Not really.

Q And what did the author say about any recommendations

11:57:22 about how to manage patients who have a strut in their pulmonary artery?

A So the authors have observed these struts are stable over time. Patients are asymptomatic. They have not seen any real adverse events associated with these little wires. Once

11:57:47 they land in there, they stay stable over time.

So their recommendation was that from a clinical point of view, that they should stay in place. They didn't recommend to remove them from a clinical point of view. But if the patient wants them removed, that would be an indication to remove them. So the patient had to really almost like insist on removing them, and then they would remove them. But from a clinical point of view, there was no reason, according to them, to remove it.

Q And, Dr. Stein, today, in 2018, what would your recommendation be to Mrs. Jones if she was your patient about what to do about that strut?

A If she were my patient, I would encourage her and I would say that she does indeed have a strut in the pulmonary artery, but luckily, based on my own experience and based on the literature, there's absolutely no evidence that these structures cause damage at any time.

If she were a new patient of mine I would probably want to follow her for a few months clinically to make sure that she's not getting worse clinically. I would recommend some imaging to prove that it hasn't changed.

With Ms. Jones we actually have the proof of a year that the strut has stayed in stable position. So that would be good enough for me. I would recommend against removing it and I would recommend that she just lives her life without any worries.

11:59:25 Q And, Doctor, do you hold all the opinions that you've given today to a reasonable degree of medical certainty?

A I do.

MR. NORTH: Thank you. I have no further questions.

11:59:33 THE COURT: All right. Ladies and gentlemen, we'll break at this point. We'll plan to resume at 1 o'clock. We'll excuse the jury.

(The jury exited the courtroom at 11:59.)

THE COURT: All right, Counsel, as of the lunch hour

12:00:50 plaintiff has used 24 hours and 31 minutes. Defendant has used 13 hours and 37 minutes.

We'll see you at 1 o'clock.

(End of a.m. session transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 25th day of May, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter